

Exhibit K

Designation Run Report

Orms 08-16-16 Jones Trial Designations V3

Orms, Daniel 08-16-2016

Plaintiffs Designations 00:19:14

DefenseDesignations 00:04:56

Total Time 00:24:10



05_20_18 combo Jones V3-Orms 08-16-16 Jones Trial Designations V3

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12:19 - 12:20	Orms, Daniel 08-16-2016 (00:00:02) 12:19 I went to work for C.R. Bard 12:20 in 1997.	05_20_18 combo Jones V3.0
15:11 - 15:13	Orms, Daniel 08-16-2016 (00:00:06) 15:11 Q. And you were in the position of 15:12 regional manager from 2008 until? 15:13 A. Until I left at the end of 2012.	05_20_18 combo Jones V3.0
23:10 - 23:17	Orms, Daniel 08-16-2016 (00:00:14) 23:10 Q. And part of your job in the beginning and 23:11 probably towards the end involved having discussions 23:12 with physicians, correct? 23:13 A. Uh-hum. 23:14 Q. Communicating with physicians? 23:15 A. Uh-hum. Yes, yes. I'm sorry. 23:16 Q. Communicating with physicians? 23:17 A. Correct.	05_20_18 combo Jones V3.0
24:17 - 24:24	Orms, Daniel 08-16-2016 (00:00:16) 24:17 Q. Were you provided in your training any 24:18 information to relate to physicians about bench 24:19 testing with regard to the Recovery filter? 24:20 A. No. 24:21 Q. Okay. So you were given no resources to pass 24:22 on to physicians in your region with regard to bench 24:23 testing. 24:24 A. No.	05_20_18 combo Jones V3.0
30:11 - 30:17	Orms, Daniel 08-16-2016 (00:00:14) 30:11 Q. So when you become aware or one of 30:12 your sales representatives become aware the 30:13 information is reported to Bard and it's sort of a 30:14 one-way street of information. You call them and 30:15 report it but they don't necessarily respond with 30:16 information about other injuries? 30:17 A. Correct.	05_20_18 combo Jones V3.0
32:11 - 32:17	Orms, Daniel 08-16-2016 (00:00:16) 32:11 Q. Are you aware if the Recovery filter 32:12 was ever put on hold in 2004? 32:13 A. Oh, wow. I don't remember. 32:14 Q. Okay. So you don't recall if in April of 32:15 2004 if there was an internal hold placed on the 32:16 Recovery filter not to be sold?	05_20_18 combo Jones V3.0

05_20_18 combo Jones V3-Orms 08-16-16 Jones Trial Designations V3

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32:24 - 33:1	32:17 A. I don't recall. Orms, Daniel 08-16-2016 (00:00:05)	05_20_18 combo Jones V3.10
33:3 - 33:10	32:24 Q. Had that ever happened with any 33:1 product at Bard while you were there? Orms, Daniel 08-16-2016 (00:00:15) 33:3 A. I don't recall. I don't think so. I mean, I 33:4 would have -- I think I would remember, but I don't 33:5 think so. 33:6 Q. It seems like an unusual event, correct? 33:7 A. Yes. 33:8 Q. Something that would be memorable. 33:9 A. Yeah. And I don't remember that happening, so 33:10 yeah.	05_20_18 combo Jones V3.11
44:22 - 44:23	Orms, Daniel 08-16-2016 (00:00:03) 44:22 Q. Do you know why the Recovery filter 44:23 was modified?	05_20_18 combo Jones V3.12
45:4 - 45:7	Orms, Daniel 08-16-2016 (00:00:14) 45:4 I think there 45:5 was a desire to make it more, I don't know what the 45:6 other word is, I guess so that it would sit in the cava 45:7 more firmly. I guess because of that Baptist incident,	05_20_18 combo Jones V3.13
45:10 - 45:13	Orms, Daniel 08-16-2016 (00:00:06) 45:10 Q. Okay. 45:11 A. And so they were trying to get it to anchor 45:12 more firm. 45:13 Q. So it was modified for safety reasons.	05_20_18 combo Jones V3.14
45:15 - 45:16	Orms, Daniel 08-16-2016 (00:00:04) 45:15 A. Yes, I guess to improve migration resistance 45:16 was the only thing I remember.	05_20_18 combo Jones V3.15
46:14 - 46:19	Orms, Daniel 08-16-2016 (00:00:10) 46:14 Q. But the Recovery filter was the first 46:15 filter in the United States approved for 46:16 retrievability, correct? 46:17 A. I believe so. 46:18 Q. Okay. Was that a marketing feature? 46:19 A. Yes.	05_20_18 combo Jones V3.16
47:6 - 47:14	Orms, Daniel 08-16-2016 (00:00:16) 47:6 Q. Did Bard own and manufacture and sell 47:7 every retrievable filter in the market at that time? 47:8 A. No.	05_20_18 combo Jones V3.17

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47:9 Q. Okay. So there were competitors.

47:10 A. Correct.

47:11 Q. Whereas first when Recovery came out there

47:12 were no competitors.

47:13 A. Oh, okay, okay. So, yes, so I guess the

47:14 optional filter market became more competitive.

78:10 - 78:15

Orms, Daniel 08-16-2016 (00:00:08)

05_20_18 combo Jones V3.01

78:10 Q. What's the last filter you recall

78:11 dealing with?

78:12 A. Eclipse.

78:13 Q. The Eclipse?

78:14 A. Yeah. When you said "Eclipse" it kind of

78:15 triggered a little something.

96:21 - 97:12

Orms, Daniel 08-16-2016 (00:00:32)

05_20_18 combo Jones V3.01

96:21 Q. But did anyone at Bard ever provide

96:22 you like say a report —

96:23 A. Uh-hum.

96:24 Q. — comparing failure rates between Bard's

97:1 products and competitor products, filters?

97:2 A. I don't believe so, other than what's IFU, was

97:3 it provided in the IFUs for the devices.

97:4 Q. Okay. Which does not provide comparative

97:5 rates between Bard's filters and its competitors.

97:6 A. Correct.

97:7 Q. Okay. And if you were never provided such

97:8 information you couldn't provide it to physicians,

97:9 correct?

97:10 A. Correct.

97:11 Q. Okay. And so you did not, correct?

97:12 A. Correct.

99:18 - 100:8

Orms, Daniel 08-16-2016 (00:00:29)

05_20_18 combo Jones V3.01

99:18 Q. Do you know who David Ciavarella is?

99:19 A. I vaguely remember his name, but I don't

99:20 remember what his official role is.

99:21 Q. He was the medical director for a period of

99:22 time at Bard.

99:23 A. Okay.

99:24 Q. Does that ring a bell?

100:1 A. If you tell me that. That sounds about right.

100:2 Q. Okay. Just if it sparks something else of a

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100:3 recollection about him, that's merely why I bring it
 100:4 up. When I say "ring a bell," I'm not trying to be
 100:5 facetious in any way.
 100:6 A. Okay. No, I mean, I just never had any -- any
 100:7 involvement with him at his level, if he's the medical
 100:8 director.

101:19 - 102:9 **Orms, Daniel 08-16-2016 (00:00:28)**

05_20_18 combo Jones V3.24

101:19 Q. Complaint rate MDR and complaint rate for SNF
 101:20 with regard to G2 and SNF.
 101:21 A. So was that provided to us?
 101:22 Q. Uh-hum.
 101:23 A. No.
 101:24 Q. Okay. Were you made aware that the medical
 102:1 director of Bard was asking this question of, "The
 102:2 G2's a permanent filter; we also have the SNF that has
 102:3 virtually no complaints. Why shouldn't doctors be
 102:4 using that one rather than the G2?"
 102:5 A. No.
 102:6 Q. So that information was not provided to you
 102:7 while you were on the ground in the territory selling
 102:8 or overseeing the sales of G2 filters.
 102:9 A. Correct.

105:1 - 105:7 **Orms, Daniel 08-16-2016 (00:00:14)**

05_20_18 combo Jones V3.25

105:1 Q. And when complaints are reported in
 105:2 your region, are they shared amongst the sales
 105:3 representatives in your region?
 105:4 A. Not as a matter of practice.
 105:5 Q. Okay. So that's not a policy at Bard to do
 105:6 that?
 105:7 A. No.

105:14 - 105:16 **Orms, Daniel 08-16-2016 (00:00:03)**

05_20_18 combo Jones V3.26

105:14 A. Was it shared?
 105:15 Q. Uh-hum.
 105:16 A. It would have been word of mouth.

138:18 - 138:23 **Orms, Daniel 08-16-2016 (00:00:09)**

05_20_18 combo Jones V3.27

138:18 Q. But these filters are sold to be
 138:19 placed in patients, correct?
 138:20 A. Correct.
 138:21 Q. Okay. And you're not aware of whether a
 138:22 patient would like to have the safest filter possible

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139:2 - 139:5 138:23 available implanted in them?

Orms, Daniel 08-16-2016 (00:00:09)

05_20_18 combo Jones V3 21

139:2 A. I guess I would think, yes, they would.

139:3 Q. Okay, okay. Is that a big assumption to make

139:4 on your part, being someone who's sold filters to be

139:5 used in humans for so long?

139:7 - 139:7 Orms, Daniel 08-16-2016 (00:00:00)

05_20_18 combo Jones V3 22

139:7 A. No.

143:7 - 143:7 Orms, Daniel 08-16-2016 (00:00:03)

05_20_18 combo Jones V3 23

143:7 Q. All right. Exhibit 13 to your deposition.

143:8 - 143:9 Orms, Daniel 08-16-2016 (00:00:03)

05_20_18 combo Jones V3 24

143:8 And you can take a minute to look at that.

143:9 A. Okay.

143:10 - 143:23 Orms, Daniel 08-16-2016 (00:00:26)

05_20_18 combo Jones V3 25

143:10 Q. This is an E-mail exchange between you

143:11 and Chris Smith, correct?

143:12 A. Yes.

143:13 Q. And who's Chris Smith?

143:14 A. Chris Smith was, as his title indicates, the

143:15 district manager for the southeast is the geography that

143:16 he was managing at the time.

143:17 Q. And this is dated November 9th, 2010,

143:18 correct?

143:19 A. Correct.

143:20 Q. So the Eclipse has been on the market for

143:21 approximately a year, if it was cleared in January of

143:22 2010?

143:23 A. Okay, yes.

145:7 - 145:22 Orms, Daniel 08-16-2016 (00:00:38)

05_20_18 combo Jones V3 26

145:7 Q. It says, "As we discussed on Friday,

145:8 we lost all of the Northside IVC filter business.

145:9 They had three Eclipse filter fractures in three

145:10 months as well as another penetration. I have a great

145:11 relationship with the physicians, but they do not feel

145:12 comfortable using the filter anymore. Dr. Levy called

145:13 my Friday night and we talked for quite some time but

145:14 unfortunately they have decided to stop using Eclipse.

145:15 This will be over a \$200,000 filter loss next year for

145:16 my territory. I know we have a new filter technology

145:17 coming out next year, but I wanted you to pass this

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145:18 along as to not surprise anyone. All of the defective
 145:19 devices have been reported. Please let me know if you
 145:20 need anything else. Thanks."
 145:21 Did I read that correctly?
 145:22 A. Yes.

146:8 - 146:12

Orms, Daniel 08-16-2016 (00:00:14)

05_20_18 combo Jones V3.21

146:8 Q. So in the history of the Bard retrievable
 146:9 filters the Eclipse was an improvement over the G2 and
 146:10 now it appears that there's an improvement coming out
 146:11 over the Eclipse, as we see indicated in this E-mail
 146:12 and the exhibit we just looked at, correct?

146:14 - 147:5

Orms, Daniel 08-16-2016 (00:00:33)

05_20_18 combo Jones V3.21

146:14 A. Yes, based on the E-mail.
 146:15 Q. And so the improved filter, the next
 146:16 iteration, the modification of the G2, the Eclipse is
 146:17 also starting to fail, correct?
 146:18 A. Clearly there's been these filter fractures,
 146:19 adverse runs.
 146:20 Q. And as they're discussing the new technology
 146:21 that's coming out.
 146:22 A. Yes.
 146:23 Q. But Eclipse was still being sold, correct?
 146:24 A. Yes.
 147:1 Q. Okay. Did you report any of these three
 147:2 filter fractures to anyone else, any other physicians
 147:3 in your territory, when it came up through your sales
 147:4 rep?

147:9 - 147:9

Orms, Daniel 08-16-2016 (00:00:01)

05_20_18 combo Jones V3.21

147:9 Q. This is Exhibit 14 to your deposition.

147:19 - 147:24

Orms, Daniel 08-16-2016 (00:00:09)

05_20_18 combo Jones V3.21

147:19 Q. And it's attached to an E-mail dated
 147:20 October 2nd, 2010, correct?

147:21 A. Yes.

147:22 Q. And that was within 30 days of the last
 147:23 exhibit, correct?

147:24 A. Yes.

148:10 - 149:1

Orms, Daniel 08-16-2016 (00:00:34)

05_20_18 combo Jones V3.21

148:10 Q. And you are on this E-mail, correct?

148:11 A. Yes, I am.

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148:12 Q. Okay. And the cover E-mail states, "All,
148:13 commercialization for the plan Meridian filter is
148:14 attached. Please feel free to contact me with any
148:15 questions you may have regarding the Meridian filter
148:16 or its anticipated launch at the NSM in January. The
148:17 filter team is looking forward to an exciting launch."
148:18 This E-mail is from Jeffrey Pellicio.

148:19 A. Yes.

148:20 Q. Do you know who he is?

148:21 A. Yes.

148:22 Q. Okay. Who is he?

148:23 A. He was in the filter marketing team.

148:24 Q. Filter marketing?

149:1 A. Team.

149:15 - 149:20 **Orms, Daniel 08-16-2016 (00:00:12)**

05_20_18 combo Jones V3.28

149:15 So within a month of the E-mail that
149:16 we just looked at regarding Eclipse fracture failures
149:17 and new technology coming out, they're already
149:18 discussing the new technology, correct, which seems to
149:19 be the Meridian filter?

149:20 A. Yes.

150:9 - 150:13 **Orms, Daniel 08-16-2016 (00:00:09)**

05_20_18 combo Jones V3.42

150:9 Q. So the Meridian was to be an improvement over
150:10 the Eclipse, correct?

150:11 A. Yes.

150:12 Q. And the Eclipse was an improvement over the
150:13 G2 filters, correct?

150:15 - 151:22 **Orms, Daniel 08-16-2016 (00:01:11)**

05_20_18 combo Jones V3.43

150:15 A. Yes.

150:16 Q. And the G2 filters were improvements over the
150:17 Recovery filter, correct?

150:18 A. Yes.

150:19 Q. Okay. If you look at the first page of the
150:20 commercialization plan, Bates ending 0206.

150:21 A. Uh-hum.

150:22 Q. It starts, "The commercialization plan
150:23 details launch logistics of the Meridian filter which
150:24 will launch Q1 2011 at the National Sales Meeting as
151:1 BPV's newly-designed premier retrievable filter. The
151:2 Meridian filter will completely phase out the Eclipse

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151:3 and G2 filters in 2011 and remain on the market until
 151:4 the launch of BPV's next generation filter, the
 151:5 Denali, at the end of 2012."

151:6 Did I read that properly?

151:7 A. Yes.

151:8 Q. Okay. So they're discussing these
 151:9 reiterations before they even come out but while they
 151:10 still have their older filters still on the market,
 151:11 correct?

151:12 A. Correct.

151:13 Q. Okay. And the value proposition here is
 151:14 similar to what we just read. "The Meridian (Eclipse
 151:15 anchors) filter will retain the advantages of G2, G2X,
 151:16 and Eclipse, including the retrieval indication while
 151:17 improving caudal migration resistance. The addition
 151:18 of caudal anchors should limit the amount of tilt
 151:19 which may reduce the likelihood of penetration and
 151:20 fracture."

151:21 Did I read that correctly?

151:22 A. Yes.

162:3 - 162:5 **Orms, Daniel 08-16-2016 (00:00:11)**

05_20_18 combo Jones V3.41

162:3 Meaning, the doctors look to you to advise
 162:4 them about everything that is available to you about
 162:5 the product; true?

162:7 - 162:8 **Orms, Daniel 08-16-2016 (00:00:07)**

05_20_18 combo Jones V3.41

162:7 A. Yes.

162:8 Q. The good, the bad and the indifferent.

162:10 - 162:14 **Orms, Daniel 08-16-2016 (00:00:15)**

05_20_18 combo Jones V3.41

162:10 A. From my experience, physicians want data that
 162:11 they can rely on.

162:12 Q. Which means open, frank, honest
 162:13 communications.

162:14 A. About data they can rely on, yes.

167:20 - 167:24 **Orms, Daniel 08-16-2016 (00:00:12)**

05_20_18 combo Jones V3.41

167:20 Q. Well, I guess I'm trying to figure out, was
 167:21 there somebody within Bard that was communicating to
 167:22 other people in Bard that there were a series of
 167:23 events going on with say the Recovery. We talked
 167:24 about the Recovery before.

168:2 - 168:2 **Orms, Daniel 08-16-2016 (00:00:01)**

05_20_18 combo Jones V3.41

05_20_18 combd Jones V3-Orms 08-16-16 Jones Trial Designations V3

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172:14 - 172:15	168:2 A. To my knowledge, no. Orms, Daniel 08-16-2016 (00:00:04)	05_20_18 combd Jones V3.47
172:17 - 172:21	172:14 Q. somewhere along the line, Bard 172:15 learned that tilting in a filter was a bad thing. Orms, Daniel 08-16-2016 (00:00:07) 172:17 A. Yeah, it wasn't optimal. I mean, there's 172:18 better -- an improvement to be had. 172:19 Q. It was undesirable in a filter, correct? 172:20 *** 172:21 A. Yes.	05_20_18 combd Jones V3.48
173:14 - 173:19	Orms, Daniel 08-16-2016 (00:00:21) 173:14 Q. Well, if there was a group in Bard that was 173:15 aware of events with the filter such as the Recovery, 173:16 and was aware that the Recovery was tilting and either 173:17 causing injuries or causing potential complications to 173:18 patients, that's information that you would expect to 173:19 be given to you people in sales to use, correct?	05_20_18 combd Jones V3.49
173:21 - 173:21	Orms, Daniel 08-16-2016 (00:00:03) 173:21 A. Yeah, it would be good to know.	05_20_18 combd Jones V3.50
174:13 - 174:16	Orms, Daniel 08-16-2016 (00:00:09) 174:13 Q. And so you could understand why doctors would 174:14 rely on you to -- to, No. 1, assume that you're in the 174:15 know and that you would communicate that to the 174:16 doctor, correct?	05_20_18 combd Jones V3.51
174:18 - 174:18	Orms, Daniel 08-16-2016 (00:00:01) 174:18 A. Yes.	05_20_18 combd Jones V3.52
174:24 - 175:10	Orms, Daniel 08-16-2016 (00:00:32) 174:24 A. If the data's meaningful and reliable, yes. 175:1 Q. And so that's why it would be reasonable for 175:2 you, in the position you were at, and for your 175:3 salespeople, to be advised from whoever in Bard was 175:4 tracking events and knew what complications or 175:5 potential complications those events were causing; 175:6 fair? 175:7 A. Yes. 175:8 Q. And from what you told us today, that really 175:9 wasn't something that was going on. 175:10 A. No. As a matter of practice, no.	05_20_18 combd Jones V3.53
176:15 - 177:1	Orms, Daniel 08-16-2016 (00:00:29) 176:15 Q. Well, how would the conversation go?	05_20_18 combd Jones V3.54

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176:16 A. The conversation would probably go, again, the
 176:17 physician makes the decision to use any device based on
 176:18 risk reward, benefit to the patient, and whether it was
 176:19 Recovery or G2 or G2X or whatever other iterations, the
 176:20 devices were providing a significant benefit to the
 176:21 patient. The doctor has to weigh that versus the risk
 176:22 of the device. And if the risk of the device is within
 176:23 the guidelines of that technology, then that's all that
 176:24 I can do. From a sales perspective, that's all that I
 177:1 can worry about.

177:9 - 177:11 Orms, Daniel 08-16-2016 (00:00:05)

05_20_18 combo Jones V3.01

177:9 If Bard is aware of problems, with for
 177:10 example the Recovery, I'm saying, that's something you
 177:11 would expect them to advise you; true?

177:13 - 177:15 Orms, Daniel 08-16-2016 (00:00:06)

05_20_18 combo Jones V3.01

177:13 A. If -- if Bard is aware of problems that are
 177:14 outside of the reporting guidelines, yes, that's what --
 177:15 I would want to know that.

178:3 - 178:10 Orms, Daniel 08-16-2016 (00:00:12)

05_20_18 combo Jones V3.01

178:3 Q. And you want to be open and you want to be
 178:4 honest.
 178:5 A. And I answered exactly the way I just told you,
 178:6 and I said as far as I know they're well within the SIR
 178:7 guidelines.
 178:8 Q. Okay.
 178:9 A. And the physicians were happy. That was all
 178:10 they wanted to know.

182:19 - 182:22 Orms, Daniel 08-16-2016 (00:00:09)

05_20_18 combo Jones V3.01

182:19 Q. And nobody ever communicated to you about
 182:20 trends that Bard became aware of in terms of events
 182:21 that were associated with the Recovery filter,
 182:22 correct?

182:24 - 183:1 Orms, Daniel 08-16-2016 (00:00:02)

05_20_18 combo Jones V3.01

182:24 A. So, yeah, we were not communicated this
 183:1 information.

208:19 - 208:22 Orms, Daniel 08-16-2016 (00:00:06)

05_20_18 combo Jones V3.01

208:19 Q. Does Bard have a
 208:20 responsibility to warn if it becomes aware of a danger
 208:21 associated with its filters? Yes or no.
 208:22 A. Yes.

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222:4 - 222:4

Orms, Daniel 08-16-2016 (00:00:02)

05_20_18 combo Jones V3.01

222:4 Q. Here you go. Exhibit 16.

222:13 - 222:23

Orms, Daniel 08-16-2016 (00:00:25)

05_20_18 combo Jones V3.02

222:13 Q. Now, what we're looking at is a memorandum

222:14 entitled, subject, Monthly Management Report, correct?

222:15 A. Yes.

222:16 Q. And it's prepared by Jim Beasley, right?

222:17 A. Yes.

222:18 Q. And it's March 8, 2010, is the date. Do you

222:19 see that?

222:20 A. Yes.

222:21 Q. And at that time you were still responsible

222:22 for filters; true?

222:23 A. I believe so. Yes, yes.

05_20_18 combo Jones V3.03

223:10 - 224:13

Orms, Daniel 08-16-2016 (00:01:07)

223:10 Q. And what we're looking at is a fairly lengthy

223:11 document that Jim Beasley has prepared, correct?

223:12 A. Yes.

223:13 Q. Six pages, and then an additional 14 pages of

223:14 attachments, right?

223:15 A. Yes.

223:16 Q. And he calls it, subject, Monthly Management

223:17 Report, right?

223:18 A. Correct.

223:19 Q. And Jim Beasley at that time, what was his

223:20 position?

223:21 A. I believe he was still the president of the

223:22 division.

223:23 Q. President of —

223:24 A. Bard Peripheral Vascular.

224:1 Q. And his report is entitled Monthly Management

224:2 Report. Were you, as a district manager, responsible

224:3 to submit reports on a monthly basis?

224:4 A. I believe so.

224:5 Q. What type of reports?

224:6 A. Well, probably something that looks, probably

224:7 not similar to this, but probably, if I remember

224:8 correctly, probably something shorter than this, but to

224:9 my direct report.

224:10 Q. So it would be a report about your district

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	224:11 and about all the goings on. You would have to 224:12 prepare something and send it up the chain, right? 224:13 A. Yeah.	04_01_18 combo Jones V2 01
228:14 - 228:15	Orms, Daniel 08-16-2016 (00:00:03) 228:14 Q. Now, "reopening doors". What does that mean 228:15 to you?	05_20_18 combo Jones V3 01
228:17 - 228:18	Orms, Daniel 08-16-2016 (00:00:05) 228:17 A. It says "reopening doors with customers," so 228:18 probably getting back into accounts that --	05_20_18 combo Jones V3 01
228:23 - 229:5	Orms, Daniel 08-16-2016 (00:00:21) 228:23 Q. I mean, as a district manager you never 228:24 intended to ever eliminate that organization as a 229:1 potential opportunity, right? 229:2 A. Not totally. 229:3 Q. I mean, your job, like Bard's goal, was to 229:4 increase customer bases, to increase profits, increase 229:5 quotas, right?	05_20_18 combo Jones V3 01
229:7 - 229:24	Orms, Daniel 08-16-2016 (00:00:47) 229:7 A. Yeah; our job was to hit our sales target. 229:8 Q. Meaning there were times where you would go 229:9 and approach and try to reopen doors that might have 229:10 been closed. 229:11 A. Yes. 229:12 Q. And the Eclipse was one way that salespeople 229:13 could reopen doors that were shut. 229:14 A. Depending on the account, potentially, yeah. 229:15 Any iteration, any launch. 229:16 Q. Well, again, the Eclipse came to you, was 229:17 told to you that it had features that were over and 229:18 above its predecessor devices, correct? 229:19 A. Yes. 229:20 Q. Something that you could and your people in 229:21 your sales force could promote as new and improved, 229:22 right? 229:23 A. Yes. 229:24 Q. Safer.	05_20_18 combo Jones V3 01
230:5 - 230:6	Orms, Daniel 08-16-2016 (00:00:02) 230:5 Q. True?	05_20_18 combo Jones V3 01
230:23 - 231:4	230:6 A. New and improved, yes. Orms, Daniel 08-16-2016 (00:00:16)	05_20_18 combo Jones V3 01

05_20_18 combo Jones V3-Orms 08-16-16 Jones Trial Designations V3

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230:23 Q. He goes on to say, "Difficult comps will
230:24 continue until the June time frame and the product
231:1 category will remain a drag on the division's
231:2 performance until that time."
231:3 With all your experience in sales, what does
231:4 that mean to you?

231:7 - 231:9

Orms, Daniel 08-16-2016 (00:00:07)

05_20_18 combo Jones V3.73

231:7 A. It means, when he's saying the product will
231:8 remain a drag, it means it's not growing as fast as
231:9 maybe the other areas.

240:3 - 240:5

Orms, Daniel 08-16-2016 (00:00:08)

05_20_18 combo Jones V3.74

240:3 Q. And the G2 filter was told to you and
240:4 marketed by your salespeople that it was going to be
240:5 resistant to caudal migration, right?

240:7 - 240:7

Orms, Daniel 08-16-2016 (00:00:01)

05_20_18 combo Jones V3.75

240:7 A. Resistant to, yes;

240:7 - 240:8

Orms, Daniel 08-16-2016 (00:00:02)

05_20_18 combo Jones V3.76

240:7 A. but all filters do all of
240:8 those

241:15 - 241:18

Orms, Daniel 08-16-2016 (00:00:05)

05_20_18 combo Jones V3.76

241:15 Q. And resistant to tilt.

241:16 A. You know, I mean, again, all these adverse
241:17 events are -- are components of every filter on the
241:18 market.

242:6 - 242:8

Orms, Daniel 08-16-2016 (00:00:11)

05_20_18 combo Jones V3.77

242:6 Is it your understanding that the G2 and the
242:7 G2 Express were designed to be tilt resistant --
242:8 A. Yes.

242:10 - 242:11

Orms, Daniel 08-16-2016 (00:00:03)

05_20_18 combo Jones V3.78

242:10 A. An improvement over the previous iteration,
242:11 yes.

248:15 - 248:19

Orms, Daniel 08-16-2016 (00:00:13)

05_20_18 combo Jones V3.77

248:15 Q. Well, you would have expected most of the
248:16 effort to have been on Eclipse, especially if the
248:17 Eclipse had new features that were better performance
248:18 and safer than the G2, right?
248:19 A. Yeah.

248:22 - 249:12

Orms, Daniel 08-16-2016 (00:00:42)

05_20_18 combo Jones V3.77

248:22 Q. -- we just went through a series of injuries
248:23 in the prior report by Mr. Beasley where he writes

05_20_18 combo Jones V3-Orms 08-16-16 Jones Trial Designations V3

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248:24 about injuries and events specific to the G2 in the
249:1 month of March, right?

249:2 A. Yes.

249:3 Q. And the whole reason that Bard was developing
249:4 new filters was to make sure that doctors knew that
249:5 they were on top of things, making things safer than
249:6 the predecessors, right?

249:7 A. Yes.

249:8 Q. And that's important to you, as a district
249:9 manager, because that's how you promote it, right?

249:10 A. That's how we promote what?

249:11 Q. Your filters.

249:12 A. Yeah, as improvements.

253:23 - 254:2 **Orms, Daniel 08-16-2016 (00:00:10)**

05_20_18 combo Jones V3.71

253:23 Q. And you knew in this time frame, from what
253:24 you've seen today for the first time, you know now,
254:1 that tilting and migration were dangerous to patients,
254:2 correct?

254:4 - 254:7 **Orms, Daniel 08-16-2016 (00:00:16)**

05_20_18 combo Jones V3.72

254:4 A. At times, yes.

254:5 Q. And that tilting and perforation and
254:6 migration were caused by a lack of stability in the
254:7 filters; true?

254:9 - 254:16 **Orms, Daniel 08-16-2016 (00:00:24)**

05_20_18 combo Jones V3.73

254:9 A. Yeah, to a great extent, yes. Yes, to a great
254:10 extent.

254:11 Q. And when Bard -- when Bard developed the
254:12 Eclipse and told you to go out and promote it and get
254:13 your sales team on it, No. 1, you expected that Bard
254:14 had thoroughly tested and evaluated the Eclipse for
254:15 safety, right?

254:16 A. Yes.

258:17 - 258:19 **Orms, Daniel 08-16-2016 (00:00:08)**

05_20_18 combo Jones V3.74

258:17 Q. Well, no, follow me. You believed and
258:18 trusted Bard to thoroughly test the G2 for safety and
258:19 efficacy, right?

258:21 - 259:6 **Orms, Daniel 08-16-2016 (00:00:43)**

05_20_18 combo Jones V3.75

258:21 A. Yes.

258:22 Q. And it was that expectation that you had that
258:23 gave you the credibility with the doctor, the doctors

05_20_18 combo Jones V3-Orms 08-16-16 Jones Trial Designations V3

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258:24 you sold the product to, to give each doctor what you

259:1 believed was accurate information about the G2; fair?

259:2 A. Yes.

259:3 Q. And if, unbeknownst to you, Bard did not

259:4 thoroughly test the G2 for efficacy or safety, that

259:5 would cause you to give inaccurate information to the

259:6 doctor if you believed otherwise; true?

259:8 - 259:15 Orms, Daniel 08-16-2016 (00:00:18)

05_20_18 combo Jones V3.24

259:8 A. If unbeknownst to me they did not do their due

259:9 diligence?

259:10 Q. Yes.

259:11 A. They didn't follow kind of the guidelines and

259:12 the rules of the road?

259:13 Q. Yes.

259:14 A. Yeah, I guess if they're doing something wrong

259:15 and I'm communicating what they're telling me, then yes.

264:1 - 264:3 Orms, Daniel 08-16-2016 (00:00:06)

05_20_18 combo Jones V3.25

264:1 Q. Dan, I have a few more questions for you

264:2 today. The first is, where do you live?

264:3 A. Here in Miami, Florida.

264:18 - 265:3 Orms, Daniel 08-16-2016 (00:00:29)

05_20_18 combo Jones V3.26

264:18 Q. Can you briefly tell us about your

264:19 educational background? I know you mentioned it a

264:20 little bit earlier.

264:21 A. Okay. Yeah, I went to high school here in

264:22 Miami. Graduated from Miami Killian Senior High. Went

264:23 to the University of Florida in Gainesville for four

264:24 years, 1984 through '88, and shortly thereafter got into

265:1 my career as a salesperson.

265:2 Q. You worked for Bard for about 15 years?

265:3 A. Yes, from '97 to 2012.

265:18 - 266:2 Orms, Daniel 08-16-2016 (00:00:19)

05_20_18 combo Jones V3.27

265:18 Q. At any point during your time at Bard did you

265:19 work on the design and development of products?

265:20 A. No.

265:21 Q. Did you have any role in tracking or

265:22 analyzing adverse events?

265:23 A. No.

265:24 Q. Did any of your job responsibilities involve

266:1 determining rates of complications with Bard's

05_20_18 combo Jones V3-Orms 08-16-16 Jones Trial Designations V3

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266:5 - 266:15	<p>266:2 filters?</p> <p>Orms, Daniel 08-16-2016 (00:00:27)</p> <p>266:5 A. No, no.</p> <p>266:6 Q. How about competitor filters?</p> <p>266:7 A. No.</p> <p>266:8 Q. Was evaluating adverse event reports part of</p> <p>266:9 your job responsibilities?</p> <p>266:10 A. No, it was not.</p> <p>266:11 Q. So all of the questions that you were asked</p> <p>266:12 today about should Bard have told certain information</p> <p>266:13 to you, is it part of your job responsibilities when</p> <p>266:14 you were a district manager and later as a regional</p> <p>266:15 manager to make that determination?</p>	05_20_18 combo Jones V3.1
266:17 - 266:17	<p>Orms, Daniel 08-16-2016 (00:00:01)</p> <p>266:17 A. No, it was not.</p>	05_20_18 combo Jones V3.1
267:1 - 267:5	<p>Orms, Daniel 08-16-2016 (00:00:16)</p> <p>267:1 Q. How many different medical devices did you</p> <p>267:2 work with at any given time while you were at Bard?</p> <p>267:3 A. Probably 25 to 30 different -- different</p> <p>267:4 devices, device; balloons, catheters, stents, filters,</p> <p>267:5 wires.</p>	05_20_18 combo Jones V3.1
267:18 - 267:19	<p>Orms, Daniel 08-16-2016 (00:00:02)</p> <p>267:18 Q. Was there an entire department at Bard who</p> <p>267:19 dealt with complaint files?</p>	05_20_18 combo Jones V3.1
267:21 - 268:9	<p>Orms, Daniel 08-16-2016 (00:00:28)</p> <p>267:21 A. Yeah. I think it's either quality or field</p> <p>267:22 assurance or whoever it is that we talked about.</p> <p>267:23 Q. And to your understanding part of that</p> <p>267:24 department's role is to analyze those complaint files;</p> <p>268:1 is that right?</p> <p>268:2 A. Yeah, to my limited understanding.</p> <p>268:3 Q. During the course of your career you have</p> <p>268:4 also worked at Ethicon, Steris, and now you're at</p> <p>268:5 Abbott; is that right?</p> <p>268:6 A. Yes.</p> <p>268:7 Q. At any of these companies did the companies</p> <p>268:8 provide you with individual complaint files for</p> <p>268:9 products that you were selling?</p>	05_20_18 combo Jones V3.1
268:11 - 268:14	<p>Orms, Daniel 08-16-2016 (00:00:08)</p> <p>268:11 A. No, I was not provided with any of them.</p>	05_20_18 combo Jones V3.1

05_20_18 combo Jones V3-Orms 08-16-16 Jones Trial Designations V3

Page/Line	Source	ID
	268:12 Q. Did any of these companies provide you with 268:13 MAUDE data to share with physicians? 268:14 A. No.	05_20_18 combo Jones V3.04
282:18 - 283:10	Orms, Daniel 08-16-2016 (00:00:46) 282:18 Q. Based on your experience, what are the 282:19 sources from which physicians get their information 282:20 that they use to make decisions about patient 282:21 treatment? 282:22 A. The top two are one is certainly the clinical 282:23 trial data, so level one data from randomized clinical 282:24 trials. Behind that is peer-to-peer, communications, 283:1 conferences, journals, articles that are peer reviewed 283:2 by their -- by their peers. And that's why they have -- 283:3 they carry weight with a physician. So those are really 283:4 the top two areas that they look for I think when making 283:5 a decision. 283:6 Q. Do you believe that physicians rely on 283:7 medical device manufacturers as the primary source of 283:8 information regarding complications associated with 283:9 the medical devices? 283:10 A. No.	
284:16 - 284:18	Orms, Daniel 08-16-2016 (00:00:09) 284:16 Q. We discussed certain adverse events of IVC 284:17 filters during today's deposition, including 284:18 perforation, fracture, migration, tilting	05_20_18 combo Jones V3.11
284:19 - 285:5	Orms, Daniel 08-16-2016 (00:00:23) 284:19 Do you remember those questions during the 284:20 course of today? 284:21 A. Yes, I do. 284:22 Q. Are those adverse events risks that are 284:23 associated with the G2X filter? 284:24 A. Yeah. I mean, those were adverse events -- 285:1 285:2 A. -- that were associated with every -- eery 285:3 filter on the market that's included in every -- every 285:4 one of their IFUs. Physicians are well aware of those 285:5 -- that potential for adverse events.	05_20_18 combo Jones V3.19
285:17 - 285:21	Orms, Daniel 08-16-2016 (00:00:12) 285:17 Q. In your experience in your 15 years at Bard, 285:18 and to your understanding, did physicians know about	05_20_18 combo Jones V3.27

05_20_18 combo Jones V3-Orms 08-16-16 Jones Trial Designations V3

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285:19 the risks of IVC filters to include perforation,
285:20 fracture, migration, tilting, and irretrievability of
285:21 the filter?

285:23 - 286:4

Orms, Daniel 08-16-2016 (00:00:16)

05_20_18 combo Jones V3.17

285:23 A. Yes. And that's specifically why I kept
285:24 referring to the, in this particular case, the SIR
286:1 guidelines. If the SIR, and this is the Society of
286:2 major body of interventionalists weren't aware of them
286:3 then they wouldn't have guidelines already established
286:4 for adverse events.

300:4 - 301:5

Orms, Daniel 08-16-2016 (00:00:40)

05_20_18 combo Jones V3.18

300:4 Did you ever have possession of any of Bard's
300:5 bench testing?

300:6 A. No.

300:7 Q. Okay. With regard to any of its IVC filters.

300:8 A. No.

300:9 Q. Whether retrievable or permanent.

300:10 A. None.

300:11 Q. Okay. And therefore you didn't share any

300:12 results of its bench testing on any of its filters

300:13 with physicians --

300:14 A. No.

300:15 Q. -- that you recall. Including those at

300:16 Cleveland Clinic?

300:17 A. No.

300:18 Q. Were you ever informed that the G2 filter

300:19 failed its migration resistant testing when compared

300:20 to the SNF?

300:21 ***

300:22 A. Was I informed of that?

300:23 Q. Uh-hum.

300:24 A. No.

301:1 Q. You were never informed of that.

301:2 A. I don't believe so.

301:3 Q. Okay. Was that something you would have

301:4 known wanting to sell the product when you're

301:5 marketing both of those products in your territory?

301:7 - 301:10

Orms, Daniel 08-16-2016 (00:00:12)

05_20_18 combo Jones V3.19

301:7 A. Is that something I would have wanted to know?

301:8 I guess it would have been beneficial to know.

05_20_18 combo Jones V3-Orms 08-16-16 Jones Trial Designations V3

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301:9 Q. Okay. I'm sorry?

301:10 A. It would have been beneficial to know.

Plaintiffs Designations = 00:19:14

DefenseDesignations = 00:04:56

Total Time = 00:24:10

Exhibit L

Designation Run Report

Raji-Kubba 07-18-16 Trial depo designations V8

Raji-Kubba, Abtiha 07-18-2016

Plaintiffs Designations 00:11:21

Defense Designations 00:04:09

Plaintiffs and Defense Designations 00:02:11

Total Time 00:17:41



05_21_18 Jones Combo V8-Raji-Kubba 07-18-16 Trial depo designations V8

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75:9 - 77:3

Raji-Kubba, Abtihal 07-18-2016 (00:01:59)

05_21_18 Jones Combo V8 1

75:9 Q. Do you have in front of you Exhibit 301?

75:10 A. I do.

75:11 Q. And it's an e-mail, dated May 2009.

75:12 Correct?

75:13 A. Yes.

75:14 Q. And you received it, it was addressed to

75:15 you. Right?

75:16 A. Yes.

75:17 Q. And it was written by Bill Edwards?

75:18 A. Yes.

75:19 Q. And who was Bill Edwards?

75:20 A. I am trying to go off my memory. Since he

75:21 wasn't office staff, he must have been in sales.

75:22 Q. Okay. And he also sent it to Mike Randall?

75:23 A. Yes.

75:24 Q. Do you know who he was?

75:25 A. Yeah, Mike Randall was one -- at the time

76:1 was a program manager who works in R&D.

76:2 Q. And John Ammerman got a copy. Do you know

76:3 who he is?

76:4 A. I believe he was in sales.

76:5 Q. And what -- and this e-mail is a -- about

76:6 five paragraphs long, and it starts out by talking

76:7 about a meeting that you're going -- that you were

76:8 going to have with Dr. Lynch. Correct?

76:9 A. Yes.

76:10 Q. Do you remember it -- do you remember

76:11 anything about Dr. Lynch?

76:12 A. Not Dr. Lynch, specifically, but I am

76:13 following through this, I remember a visit, and

76:14 Dr. Agarwal is the one I remember.

76:15 Q. Okay. But the point about Dr. Lynch is

76:16 he's talking about a particular process that he's

76:17 interested in hearing about, called electropolishing,

76:18 an improvement of -- of using electropolishing. Do

76:19 you see that?

76:20 A. Yes.

76:21 Q. And was that ever implemented,

76:22 electropolishing?

05_21_18 Jones Combo V8-Raji-Kubba 07-18-16 Trial depo designations V8

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76:23 A. Electropolishing was implemented after I
76:24 started.

76:25 Q. And with what product?

77:1 A. So it's on the filter, the G2 filter at
77:2 that time, and I don't remember the trade name we
77:3 launched, maybe that was Eclipse, possibly.

77:13 - 77:14

Raji-Kubba, Abtihal 07-18-2016 (00:00:04)

05_21_18 Jones Combo V8.2

77:13 Q. And the first one that did was the Eclipse?

77:14 A. The Eclipse, correct.

78:13 - 79:5

Raji-Kubba, Abtihal 07-18-2016 (00:00:35)

05_21_18 Jones Combo V8.3

78:13 Q. Why? What's it

78:14 do? What's the advantage?

78:15 A. It's -- it's actually --

78:16 Q. Does it make it shiny? Does it make it

78:17 clean --

78:18 A. As a matter --

78:19 Q. -- does it make it stronger? That's what I

78:20 am asking.

78:21 A. Yeah. As a matter of fact, it does make it

78:22 more smoother surface, if that's the way to describe

78:23 it.

78:24 Q. Is that -- is that the only thing it does?

78:25 Is that the only advantage it provides?

79:1 A. Smoother surface, in general. That's the

79:2 appearance, that's what -- you asked what does it do,

79:3 that's what it does. It's actually --

79:4 electropolishing actually smooths. It's a way to

79:5 smooth the surface of the material.

79:17 - 79:24

Raji-Kubba, Abtihal 07-18-2016 (00:00:20)

05_21_18 Jones Combo V8.4

79:17 Q. What was the advantage besides making it

79:18 smoother? Why did you want to make it smoother?

79:19 Does that -- does that make it safer?

79:20 A. Not -- no.

79:21 Q. Does it make it more durable?

79:22 A. Durable, not in the test methods. Not in

79:23 the testing. What does it -- it does -- sorry, it

79:24 doesn't.

80:2 - 80:4

Raji-Kubba, Abtihal 07-18-2016 (00:00:05)

05_21_18 Jones Combo V8.5

80:2 Q. Does it contribute to making it more

80:3 resistant to fracture?

05_21_18 Jones Combo V8-Raji-Kubba 07-18-16 Trial depo designations V8

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80:8 - 80:13 80:4 A. Not by itself.
Raji-Kubba, Abtihal 07-18-2016 (00:00:10)

05_21_18 Jones Combo V8.6

80:8 Q. I didn't ask by itself, I asked does it

80:9 contribute, in other words --

80:10 A. Sorry.

80:11 Q. -- does it, plus other steps, make the

80:12 filter more resistant to fracture?

80:13 A. I don't know -- I don't know that.

05_21_18 Jones Combo V8.8

89:24 - 90:4 **Raji-Kubba, Abtihal 07-18-2016 (00:00:05)**

89:24 Q. Okay. So what was the actual percentage

89:25 that you --

90:1 A. I don't know.

90:2 Q. -- that Bard thought was accurate?

90:3 A. I apologize, but I don't recall those

90:4 numbers at all.

05_21_18 Jones Combo V8.10

90:5 - 90:13 **Raji-Kubba, Abtihal 07-18-2016 (00:00:30)**

90:5 Q. Did Bard publish the findings of their

90:6 review?

90:7 A. I don't know, but I believe the Journal

90:8 published something like a correction or -- I don't

90:9 know what happened after that. You have to realize,

90:10 it's been a while, but I do know that -- I do know

90:11 two things, we found inaccuracies, the Journal

90:12 published something around that. And I know that we

90:13 went to the FDA and shared with them the situation.

05_21_18 Jones Combo V8.11

98:3 - 98:8 **Raji-Kubba, Abtihal 07-18-2016 (00:00:21)**

98:3 Q. You've heard it

98:4 stated that adverse event reports generally capture

98:5 only a small fraction of the full extent of the

98:6 adverse events. Correct?

98:7 A. I -- I have heard something to that effect.

98:8 I have not heard anything specific about percentages.

05_21_18 Jones Combo V8.12

116:2 - 117:14 **Raji-Kubba, Abtihal 07-18-2016 (00:02:10)**

116:2 Q. Was there anything about the G2 and the G2

116:3 Express that was -- any design changes to increase

116:4 migra -- migration resistance?

116:5 A. I do not remember that.

116:6 Q. Were there any changes to reduce tilt?

116:7 A. So, again, I'm going back to -- the Eclipse

116:8 was the first product that was launched under my --

05_21_18 Jones Combo V8-Raji-Kubba 07-18-16 Trial depo designations V8

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116:9 developed under my watch, and that had the
 116:10 electropolishing. Then after that was the Meridian,
 116:11 and after that we were developing the Denali.
 116:12 Q. And all of those three generations that
 116:13 followed the G2 were during the period that you were
 116:14 vice president of research and development?
 116:15 A. Yes. And I would not necessarily call them
 116:16 generations, because the principle of operation was
 116:17 the same. The materials were the same. There were
 116:18 some differences, except for Denali, where we did a
 116:19 lot more work in terms of change, more features. So
 116:20 we had -- that's why we had to do a clinical trial
 116:21 for it.
 116:22 Q. What were the changes -- what were the
 116:23 design changes going from the G2 to the Eclipse?
 116:24 A. Electropolishing is what I remember.
 116:25 Q. Okay. Was there anything else done that
 117:1 would affect going from the G2 to the Eclipse? Was
 117:2 there anything done that would affect migration
 117:3 resistance?
 117:4 A. The Eclipse by itself, the electropolishing
 117:5 is what I recall was -- was the main change.
 117:6 Q. And -- and that was to address what?
 117:7 A. Electropolishing, I think I mentioned
 117:8 earlier, is -- it's basically they were at the time,
 117:9 it was becoming more a standard to do
 117:10 electropolishing, something we had talked to the FDA
 117:11 about. It basically -- it makes the surface of the
 117:12 material, nitinol, smoother. So it's -- it's -- so
 117:13 it made a lot of sense to implement it. There was no
 117:14 specific benefit that we claimed at the time with it,

117:16 - 117:21

Raji-Kubba, Abtihal 07-18-2016 (00:00:13)

05_21_18 Jones Combo V8 20

117:16 Q. Why is smoother better?
 117:17 A. Smoother is just smooth.
 117:18 Q. So smooth is better because it's smooth?
 117:19 A. It's smooth. It makes it easier to, in
 117:20 general, when you're inspecting the material, it just
 117:21 makes it easier.

122:7 - 122:22

Raji-Kubba, Abtihal 07-18-2016 (00:00:56)

05_21_18 Jones Combo V8 49

122:7 Q. Do you have 305 in front of you?

05_21_18 Jones Combo V8-Raji-Kubba 07-18-16 Trial depo designations V8

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122:8 A. I do.

122:9 Q. And 305 is a -- is an e-mail that you

122:10 received a copy of. Correct?

122:11 A. Yes.

122:12 Q. In November of 2009?

122:13 A. Yes.

122:14 Q. And the person who sent it to you was Gin

122:15 Schultz. Right?

122:16 A. Yes.

122:17 Q. And she was in charge of quality assurance?

122:18 A. Yes.

122:19 Q. And she wrote to you and Bret Baird -- I'm

122:20 sorry, she wrote to you and forwarded to you an

122:21 e-mail from Bret Baird to three individuals. Right?

122:22 A. Yes.

122:23 - 123:4

Raji-Kubba, Abtihal 07-18-2016 (00:00:19)

05_21_18 Jones Combo V8.50

122:23 Q. And the e-mail that she forwarded to you --

122:24 A. Sorry, she cc'd me when she forwarded the

122:25 e-mail to Jim.

123:1 Q. Right. Correct. Thank you for correcting

123:2 that. And the e-mail that she forwarded to you was

123:3 dealing with Dr. Nicholson. Right?

123:4 A. Yes.

129:14 - 130:7

Raji-Kubba, Abtihal 07-18-2016 (00:01:13)

05_21_18 Jones Combo V8.51

129:14 Q. going from the G2 to

129:15 the Eclipse and the Meridian and the Denali, what

129:16 were the -- what were the modifications in the

129:17 design, other than electropolishing, that would

129:18 affect fracture resistance?

129:19 A. Fracture resistance. So I know -- Eclipse

129:20 we already talked, and it wasn't about fracture

129:21 resistance, it was we implemented electropolishing.

129:22 Meridian was we added caudal anchors, additional --

129:23 additional caudal anchors, and Denali was actually,

129:24 in a way, was a more -- more changes.

129:25 And, again, it's been a while since I've

130:1 looked at the engineering drawings to give you an

130:2 accurate assessment, an accurate description that is

130:3 technical of the changes, but I know that these were

130:4 the three different products that were introduced.

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130:5	Q. Yes. The names are Meridian, Denali, and	
130:6	Eclipse.	
130:7	A. Eclipse, Meridian, and then Denali.	05_21_18 Jones Combo V8 22
131:23 - 132:11	Raji-Kubba, Abtihal 07-18-2016 (00:00:57)	
131:23	Q. So as -- as you've gone from G2 to the	
131:24	subsequent models, I don't think I've heard you	
131:25	identify any design change that would improve	
132:1	fracture resistance.	
132:2	A. There was not a specific change to	
132:3	performance criteria, and the way we make claims, it	
132:4	has to be supported by a change to the performance	
132:5	criteria. Again, going off my memory, I do not	
132:6	recall. I know for a fact with Eclipse there was	
132:7	none. And I know with Meridian we basically, simply	
132:8	stated, we added anchors to it. We did not make	
132:9	claims based -- again, going off my memory, I'll have	
132:10	to look at the test itself. I don't remember us	
132:11	changing the performance criteria or test methods.	05_21_18 Jones Combo V8 23
160:4 - 160:6	Raji-Kubba, Abtihal 07-18-2016 (00:00:04)	
160:4	Q. Now, I want to go back and talk a little	
160:5	bit more about electropolish.	
160:6	A. Yes.	05_21_18 Jones Combo V8 24
161:22 - 161:23	Raji-Kubba, Abtihal 07-18-2016 (00:00:07)	
161:22	Q. Did Bard expect to see any improvements in	
161:23	the product with respect to any of the failure modes?	05_21_18 Jones Combo V8 25
162:2 - 162:11	Raji-Kubba, Abtihal 07-18-2016 (00:00:17)	
162:2	THE WITNESS: We did not make any claims or	
162:3	change the performance criteria.	
162:4	BY MR. MANKOFF:	
162:5	Q. Okay. But I'm asking a slightly different	
162:6	question. I'm asking whether Bard expected to see	
162:7	any benefits, other than a smoother surface?	
162:8	A. Bard in its totality? Who -- who do you	
162:9	exactly mean at Bard?	
162:10	Q. Let's start with you.	
162:11	A. I -- I did not.	05_21_18 Jones Combo V8 26
162:16 - 163:3	Raji-Kubba, Abtihal 07-18-2016 (00:00:36)	
162:16	Q. You did not expect any benefits from the	
162:17	electropolish, other than a smoother surface?	
162:18	A. That's why we did not change performance	

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162:19 criteria. That's why we did not put a claim in our
 162:20 submission for any changes in performance.
 162:21 Q. Okay. So you didn't expect it to reduce
 162:22 the -- or, rather, increase the migration resistance
 162:23 of the filter?

162:24 A. Not specifically, no.

162:25 Q. And you didn't expect it to reduce the
 163:1 fracture rate of the filter?

163:2 A. Not -- not the electropolishing by itself,
 163:3 no.

167:11 - 168:2

Raji-Kubba, Abtihal 07-18-2016 (00:00:49)

167:11 Q. -- when you took the G2X filter and made
 167:12 one change to it, which was electropolish, it did not
 167:13 improve on the fracture rate or fracture resistance
 167:14 or migration resistance or corrosion resistance of
 167:15 the filter; is that correct?

167:16 A. It met the same performance criteria, so it
 167:17 did not change the performance criteria.

167:18 Q. Okay. But I'm asking a slightly different
 167:19 question, which is whether when you took the G2X
 167:20 filter and added electropolish, that was the only
 167:21 change to get to the Eclipse. Correct?

167:22 A. Yes.

167:23 Q. So when you did that, it did not improve
 167:24 the fracture resistance, the migration resistance, or
 167:25 corrosion resistance of the filter; is that correct?

168:1 A. I don't know that it did. There's no
 168:2 evidence.

168:9 - 168:12

Raji-Kubba, Abtihal 07-18-2016 (00:00:10)

168:9 Q. Do you know if anyone else at Bard thought
 168:10 that it improved on any of those parameters?

168:11 A. I cannot speak on behalf of every scientist
 168:12 at Bard.

173:5 - 173:16

Raji-Kubba, Abtihal 07-18-2016 (00:00:44)

173:5 Q. did Bard implement
 173:6 electropolishing on the G2X, because that's -- its
 173:7 competitors had electropolish filters?

173:8 A. That is not necessarily the reason exactly.
 173:9 I don't remember, by the way, if all -- all its
 173:10 competitors or every one on the market had

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173:11 electropolishing. So I can't speak to that. I can
 173:12 speak to -- it was something that was being done on
 173:13 stents, and they were nitinol, so it made sense, as a
 173:14 company, since we also had a stent line, and we were
 173:15 doing electropolishing, it made sense for us to apply
 173:16 the same manufacturing practices.

174:4 - 174:5

Raji-Kubba, Abtihal 07-18-2016 (00:00:01)

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174:4 MR. MANKOFF: I'm going to mark the next
 174:5 exhibit.

174:9 - 175:8

Raji-Kubba, Abtihal 07-18-2016 (00:01:06)

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174:9 Q. I'm showing you Exhibit 307, which appears
 174:10 to be a memo involving Eclipse marketing claims. Do
 174:11 you see that?

174:12 A. Uh-huh.

174:13 Q. Have you seen this document?

174:14 A. I'm trying to remember it. Not
 174:15 specifically.

174:16 Q. Do you see where it says "The
 174:17 electropolished finish of the equipped filter
 174:18 provides an ultra-smooth surface finish, minimizing
 174:19 micro imperfections." It goes on to say "Bench
 174:20 testing demonstrates a 60 percent improvement of
 174:21 fatigue resistance when compared to
 174:22 non-electropolished filters."

174:23 A. Yes, I see that.

174:24 Q. So as far as you recall, there was no
 174:25 improvement in fatigue resistance. Correct?

175:1 A. If you read this correctly it says, "While
 175:2 a marketing claim was not initially pursued, bench
 175:3 testing showed that electropolishing significantly
 175:4 improved fatigue resistance compared to the
 175:5 non-electropolished G2X filter." And then bench
 175:6 testing showed that, but initially, again, we tested
 175:7 it to the confidence level as the very baseline with
 175:8 G2.

176:4 - 176:12

Raji-Kubba, Abtihal 07-18-2016 (00:00:20)

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176:4 Q. So it's your testimony that there is
 176:5 substantial improvement in the fatigue resistance --

176:6 A. I --

176:7 Q. -- of the electropolished filter?

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176:8 A. I don't have the test results in front of
 176:9 me, but knowing our process, if there wasn't data, we
 176:10 would not be making this claim, and I don't know, by
 176:11 the way, where this ended up being, but we would not
 176:12 make that claim. That's the process.

178:2 - 178:10 **Raji-Kubba, Abtihal 07-18-2016 (00:00:26)**

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178:2 Q. I'd like to ask the same question, which
 178:3 is, is it your testimony that the electropolish
 178:4 filter is a substantial improvement with respect to
 178:5 fatigue resistance over the G2?

178:6 A. It is my testimony that post approval and
 178:7 the initial design of the -- the initial testing of
 178:8 the Eclipse filter, that there is evidence, there was
 178:9 data that showed 60 percent improvement of the
 178:10 fatigue resistance.

204:12 - 204:21 **Raji-Kubba, Abtihal 07-18-2016 (00:00:26)**

05_21_18 Jones Combo V8 32

204:12 Q. I'm showing you an e-mail, Exhibit 308, the
 204:13 e-mail on the bottom was sent from Gin Schultz to you
 204:14 and some others. Do you see that?

204:15 A. Uh-huh.

204:16 Q. The subject is "Potential actions." Do you
 204:17 see that?

204:18 A. Yes.

204:19 Q. Do you recall getting this e-mail?

204:20 A. Not specifically, but allow me to read it
 204:21 to know what it is about, potential actions for what.

204:25 - 205:19 **Raji-Kubba, Abtihal 07-18-2016 (00:00:52)**

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204:25 Q. Do you know Gin Schultz?

205:1 A. Yes, I do.

205:2 Q. And who is he or she?

205:3 A. She's -- she was the head of quality at the
 205:4 time for Bard Peripheral Vascular.

205:5 Q. Now, do you see where she lists as a
 205:6 potential action recalling RNF?

205:7 A. I see a list of potential actions. I don't
 205:8 know in what context or what was behind this e-mail.

205:9 Q. Do you see where it says "recall RNF"?

205:10 A. Where? As a potential action or what?

205:11 Q. It's listed on page 2 about five lines
 205:12 down.

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205:13 A. Yes, I see that.

205:14 Q. And this was in 2010, the Recovery was no

205:15 longer being sold at that time. Correct?

205:16 A. Correct.

205:17 Q. Okay. And do you see where she mentions

205:18 sending out Dear Colleague letters recommending

205:19 annual monitoring as a potential action?

205:21 - 206:1 **Raji-Kubba, Abtiha 07-18-2016 (00:00:15)**

05_21_18 Jones Combo V8.19

205:21 THE WITNESS: I don't know -- sending

205:22 out -- and monitoring. Okay, I see that.

205:23 BY MR. MANKOFF:

205:24 Q. And below that it says "Monitor if no or

205:25 asymptomatic fragment." Do you see that?

206:1 A. I see that.

206:5 - 206:16 **Raji-Kubba, Abtiha 07-18-2016 (00:00:36)**

05_21_18 Jones Combo V8.27

206:5 Q. Did you consider any of those actions or do

206:6 you recall considering any of those actions, as we

206:7 sit here today?

206:8 A. I don't recall, specifically. By the way,

206:9 just because I don't remember in what context, what

206:10 was -- what was behind this, or --so this is part of

206:11 something else, and I'm only looking at the list, so

206:12 I can't really, it's -- it's a list of theoretical

206:13 potential actions, but I really don't know how it was

206:14 here being presented.

206:15 Q. Do you think that it would make sense to

206:16 monitor patients with RNF filters?

206:19 - 206:22 **Raji-Kubba, Abtiha 07-18-2016 (00:00:12)**

05_21_18 Jones Combo V8.28

206:19 THE WITNESS: Would it make sense, I don't

206:20 know. I'm not a clinician, so it's hard for me to

206:21 comment. I don't see these patients. I don't know

206:22 their specific conditions.

227:20 - 228:1 **Raji-Kubba, Abtiha 07-18-2016 (00:00:21)**

05_21_18 Jones Combo V8.41

227:20 Was one of the acceptance criteria for the

227:21 Eclipse filter that it was substantially equivalent

227:22 to the G2 with respect to the bench tests?

227:23 A. Yes.

227:24 Q. And did the Eclipse also have to

227:25 demonstrate substantial equivalence with the

228:1 SNF filter?

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228:4 - 228:7

Raji-Kubba, Abtihal 07-18-2016 (00:00:12)

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228:4 THE WITNESS: So there's one -- typically,
228:5 there was one predicate that we picked for that
228:6 submission to show substantial equivalence, and I
228:7 remember it being G2 Express or G2, one of the two.

Plaintiffs Designations = 00:11:21

Defense Designations = 00:04:09

Plaintiffs and Defense Designations = 00:02:11

Total Time = 00:17:41

Exhibit M

Designation Run Report

Rogers 03-21-18 Jones Trial Designations V2

Rogers, Frederick 07-18-2017

Our Designations 00:07:35

Their Designations 00:02:49

Total Time 00:10:24



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46:6 - 46:9	Rogers, Frederick 07-18-2017 (00:00:13) 46:6 Q. Now, do you understand that this 46:7 deposition that you're giving today is to discuss 46:8 Bard and its IVC filters? 46:9 A. Yes.	05_21_18 Jones Combo V2.1
60:22 - 60:25	Rogers, Frederick 07-18-2017 (00:00:12) 60:22 Q. Did Bard ever come to you and request 60:23 that you conduct a clinical trial or perform a trial 60:24 study of any of its filters? 60:25 A. Not that I recall.	05_21_18 Jones Combo V2.2
61:8 - 61:25	Rogers, Frederick 07-18-2017 (00:01:02) 61:8 Q. When you met with the panel at the 61:9 Bard summit we discussed a while ago, do you recall 61:10 any discussions about Bard performing a clinical 61:11 trial or undertaking a trial study of any of its 61:12 filters? 61:13 A. I don't recall specifically any 61:14 discussions to that extent. But I will say that 61:15 I've had a longstanding interest in doing a study on 61:16 the effectiveness of filters and, specifically, in 61:17 trauma patients. I may have talked to Bard about 61:18 that. I don't recall. 61:19 Q. You may have spoken to Bard about 61:20 that? 61:21 A. Yes, sir. 61:22 Q. But they have never, in turn, 61:23 requested that you conduct such a study of its 61:24 filters, for example, correct? 61:25 A. Not that I recall.	05_21_18 Jones Combo V2.3
106:10 - 106:14	Rogers, Frederick 07-18-2017 (00:00:20) 106:10 Q. Doctor, it's my understanding that 106:11 you are an author on an article titled, Vena Cava 106:12 Filter Use in Trauma and Rates of Pulmonary 106:13 Embolism, 2003 to 2015? 106:14 A. Yes, sir.	05_21_18 Jones Combo V2.4
106:18 - 106:19	Rogers, Frederick 07-18-2017 (00:00:05) 106:18 MR. JOHNSON: And, Amanda, we would 106:19 like to mark that as Exhibit-4053, please.	05_21_18 Jones Combo V2.5
107:1 - 107:13	Rogers, Frederick 07-18-2017 (00:00:39) 107:1 Q. Doctor, take a minute and just	05_21_18 Jones Combo V2.6

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	107:2 confirm that that is the article you are an author	
	107:3 on.	
	107:4 A. Yes, I recognize the article.	
	107:5 Q. It was published in May – I'm sorry,	
	107:6 on May 17th, 2017, in JAMA?	
	107:7 A. JAMA Surgery.	
	107:8 Q. JAMA Surgery. And JAMA stands for	
	107:9 the Journal of the American Medical Association?	
	107:10 A. Correct.	
	107:11 Q. And the article spans 12 years and	
	107:12 involved many patients; is that correct?	
	107:13 A. Yes.	
108:23 - 108:25	Rogers, Frederick 07-18-2017 (00:00:08)	05_21_18 Jones Combo V2.7
	108:23 Q. I'd like to have at least an estimate	
	108:24 as to how many trauma patients were analyzed with	
	108:25 respect to this article.	
109:5 - 109:6	Rogers, Frederick 07-18-2017 (00:00:03)	05_21_18 Jones Combo V2.7
	109:5 THE WITNESS: Probably close to 30	
	109:6 million.	
110:14 - 110:15	Rogers, Frederick 07-18-2017 (00:00:07)	05_21_18 Jones Combo V2.22
	110:14 Q. This article was designed to study	
	110:15 the effectiveness of IVC filters, correct?	
110:17 - 110:19	Rogers, Frederick 07-18-2017 (00:00:08)	05_21_18 Jones Combo V2.22
	110:17 THE WITNESS: No, I disagree with	
	110:18 that characterization. We were just noting temporal	
	110:19 trends in filter use during that time period.	
114:17 - 114:20	Rogers, Frederick 07-18-2017 (00:00:13)	05_21_18 Jones Combo V2.24
	114:17 Q. And you indicated that the patient	
	114:18 population that was looked at for purposes of this	
	114:19 article was trauma patients, correct?	
	114:20 A. Yes.	
114:21 - 114:23	Rogers, Frederick 07-18-2017 (00:00:11)	05_21_18 Jones Combo V2.8
	114:21 Q. And do you consider trauma patients	
	114:22 as a whole to be at highest risk for PE compared to	
	114:23 other patient populations?	
114:25 - 115:1	Rogers, Frederick 07-18-2017 (00:00:04)	05_21_18 Jones Combo V2.10
	114:25 THE WITNESS: I would say one of the	
	115:1 highest risk groups of patients, yes.	
117:4 - 118:5	Rogers, Frederick 07-18-2017 (00:01:24)	05_21_18 Jones Combo V2.11
	117:4 Q. And at the time you and your	

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117:5 colleagues began the study, there had been a
 117:6 precipitous drop in the use of IVC filters in trauma
 117:7 patients, correct?
 117:8 A. Well, that's what the purpose of the
 117:9 study was, was to look at the temporal trends in
 117:10 vena cava filter use.
 117:11 We had a perception that there may be
 117:12 less filters being put in. But until we, you know,
 117:13 actually did the study and analyzed the data did we
 117:14 know for sure.
 117:15 Q. And you, in fact, found that there
 117:16 had been a significant decline or drop in the use of
 117:17 IVC filters in trauma patients, correct?
 117:18 A. Yes, correct.
 117:19 Q. All right. And when you and your
 117:20 colleagues embarked on this article, you were
 117:21 expecting to see a rise or an increase in the rate
 117:22 of pulmonary embolism because of this significant
 117:23 drop in the use of IVC filters, correct?
 117:24 A. Correct.
 117:25 Q. That was your prediction, if you
 118:1 will, or your hypothesis at the start of this?
 118:2 A. Yes, sir.
 118:3 Q. And while it might have been a guess,
 118:4 it was felt to be an educated guess, that is, your
 118:5 hypothesis?

118:7 - 118:12 **Rogers, Frederick 07-18-2017 (00:00:14)**

05_21_18 Jones Combo V2.12

118:7 THE WITNESS: Yes.
 118:8 BY MR. JOHNSON:
 118:9 Q. And that's why you do the study,
 118:10 because unless you do the study predicting an
 118:11 outcome, there's nothing more than speculation and
 118:12 conjecture, correct?

118:14 - 118:23 **Rogers, Frederick 07-18-2017 (00:00:35)**

05_21_18 Jones Combo V2.12

118:14 THE WITNESS: I think that's fair,
 118:15 yes.
 118:16 BY MR. JOHNSON:
 118:17 Q. And that hypothesis was proven to be
 118:18 not true, correct?
 118:19 A. Correct.

05_21_18 Jones Combo V2-Rogers 03-21-18 Jones Trial Designations V2

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118:20	Q. That is, what you and your colleagues	
118:21	found was that, despite the significant decline in	
118:22	the use of IVC filters in trauma patients, there was	
118:23	no change in the rate of PE, correct?	
118:25 - 118:25	Rogers, Frederick 07-18-2017 (00:00:01)	05_21_18 Jones Combo V2.14
118:25	THE WITNESS: Correct.	
119:2 - 119:5	Rogers, Frederick 07-18-2017 (00:00:14)	05_21_18 Jones Combo V2.21
119:2	Q. So you and your colleagues determined	
119:3	that because of these findings, IVC filters may have	
119:4	limited utility in influencing the rates of	
119:5	pulmonary embolism, correct?	
119:7 - 119:11	Rogers, Frederick 07-18-2017 (00:00:12)	05_21_18 Jones Combo V2.22
119:7	THE WITNESS: Yes. I think the	
119:8	operative word here is "may." Because we just don't	
119:9	know, in a large patient population like this, any	
119:10	individual patient who may or may not benefit from a	
119:11	filter.	
119:17 - 119:24	Rogers, Frederick 07-18-2017 (00:00:25)	05_21_18 Jones Combo V2.12
119:17	Q. That's a pretty large patient	
119:18	population, isn't it?	
119:19	A. It certainly is, yes.	
119:20	Q. And what you folks -- and I'm	
119:21	referring to you and your colleagues -- found was	
119:22	that despite the significant decline in IVC filter	
119:23	use in trauma patients, there was no change in the	
119:24	rate of pulmonary embolism, correct?	
120:1 - 120:1	Rogers, Frederick 07-18-2017 (00:00:02)	05_21_18 Jones Combo V2.16
120:1	THE WITNESS: Correct.	
120:3 - 120:7	Rogers, Frederick 07-18-2017 (00:00:17)	05_21_18 Jones Combo V2.07
120:3	Q. And when you and your colleagues	
120:4	determined that filters may have limited utility,	
120:5	what you're referring to is they may not be	
120:6	effective in influencing the rates of pulmonary	
120:7	embolism in trauma patients?	
120:9 - 120:21	Rogers, Frederick 07-18-2017 (00:00:46)	05_21_18 Jones Combo V2.10
120:9	THE WITNESS: What we concluded,	
120:10	based on this study, was that as it currently	
120:11	stands, we are not doing a very good job in	
120:12	identifying which patients would benefit from a vena	
120:13	cava filter. I think we need to -- I think this	

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120:14 study generates more questions about what -- who is
 120:15 best served by having a prophylactic vena cava
 120:16 filter placed.

120:17 BY MR. JOHNSON:

120:18 Q. And that's because in your article,
 120:19 based on your study of all of these trauma patients,
 120:20 the placement of IVC filters did not improve the
 120:21 rates of pulmonary embolism, correct?

120:23 - 121:5 **Rogers, Frederick 07-18-2017 (00:00:25)**

05_21_18 Jones Combo V2.12

120:23 THE WITNESS: Overall -- the overall
 120:24 rate. But, again, as was noted in the study, the
 120:25 real purpose of vena cava filters is to prevent
 121:1 fatal PEs. We do not know, based on this study,
 121:2 whether or not vena cava filters were effective in
 121:3 decreasing the rate of fatal PE, which is an
 121:4 important -- you know, an important limitation of
 121:5 this study.

125:3 - 125:6 **Rogers, Frederick 07-18-2017 (00:00:21)**

05_21_18 Jones Combo V2.17

125:3 Q. And what have you done to
 125:4 better define or to optimize patient selection to
 125:5 determine whether that patient is a candidate for
 125:6 IVC filter implantation?

125:8 - 125:18 **Rogers, Frederick 07-18-2017 (00:00:48)**

05_21_18 Jones Combo V2.18

125:8 THE WITNESS: Well, since this
 125:9 article was published, I've, you know -- I've made
 125:10 it my life's work to try to identify who best would
 125:11 be served by a vena cava filter.
 125:12 Have I done it perfectly? Obviously
 125:13 not, because there still are patients who get PEs
 125:14 despite the fact that, you know, we characterize
 125:15 them as intermediate risk. And, you know, I think
 125:16 this study was a bit of an eye-opener for me because
 125:17 I really did expect that filters would impact the
 125:18 rate of PE.

125:19 - 125:22 **Rogers, Frederick 07-18-2017 (00:00:07)**

05_21_18 Jones Combo V2.19

125:19 So we have to go back to the drawing
 125:20 board and re-look at that. That's how --
 125:21 Q. And --

125:22 A. That's how medicine advances.

125:25 - 126:4 **Rogers, Frederick 07-18-2017 (00:00:17)**

05_21_18 Jones Combo V2.21

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125:25 THE WITNESS: This is, you know –
 126:1 medicine is an ongoing project. It's not static,
 126:2 you know. You don't make one determination and
 126:3 that's it; the ironclad evidence that lasts forever.
 126:4 We learn and grow as we move forward as clinicians.

126:6 - 126:10

Rogers, Frederick 07-18-2017 (00:00:20)

05_21_18 Jones Combo V2.19

126:6 Q. And, Doctor, it was an eye-opener for
 126:7 you because you were expecting this study to
 126:8 establish that the use of filters in trauma patients
 126:9 would, in fact, improve the rates of pulmonary
 126:10 embolism, correct?

126:12 - 126:16

Rogers, Frederick 07-18-2017 (00:00:18)

05_21_18 Jones Combo V2.20

126:12 THE WITNESS: Yes.

126:13 BY MR. JOHNSON:

126:14 Q. And this study that you were part of
 126:15 demonstrated that the use of IVC filters did not
 126:16 improve the rates of pulmonary embolism, correct?

126:19 - 126:19

Rogers, Frederick 07-18-2017 (00:00:01)

05_21_18 Jones Combo V2.21

126:19 Yes.

Our Designations = 00:07:35

Their Designations = 00:02:49

Total Time = 00:10:24

Exhibit N

Designation Run Report

Schultz 01-30-14 Jones Trial Designations V3

Shultz, Gin 01-30-2014

Plaintiffs Designations 00:27:23

Defense Designations 00:11:00

Total Time 00:38:23



05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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13:17 - 13:18

Shultz, Gin 01-30-2014 (00:00:01)

05_14_18 Jones Combo V3.1

13:17 Q. Good morning, Ms. Schulz.

13:18 A. Good morning.

26:11 - 26:13

Shultz, Gin 01-30-2014 (00:00:09)

05_14_18 Jones Combo V3.2

26:11 Q. And when did you first start

26:12 working at Bard?

26:13 A. 2005. October 3rd, 2005.

49:8 - 49:11

Shultz, Gin 01-30-2014 (00:00:09)

05_14_18 Jones Combo V3.3

49:8 Okay. What was your title

49:9 when you were hired at Bard?

49:10 A. I believe it was VP of

49:11 quality assurance.

50:17 - 50:24

Shultz, Gin 01-30-2014 (00:00:24)

05_14_18 Jones Combo V3.4

50:17 I also had responsibility of

50:18 monitoring the performance of the overall

50:19 system. I reported -- or had the process

50:20 of reporting out to our executive team at

50:21 BPV as well as to my supervisor who was

50:22 at corporate.

50:23 Q. Who was your supervisor?

50:24 A. Chris Ganser.

54:19 - 54:21

Shultz, Gin 01-30-2014 (00:00:02)

05_14_18 Jones Combo V3.5

54:19 Q. Okay. And you're currently

54:20 still at Bard, correct?

54:21 A. Yes.

57:24 - 58:11

Shultz, Gin 01-30-2014 (00:00:22)

05_14_18 Jones Combo V3.6

57:24 Q. Okay. I'm just asking your

58:1 opinion as a quality person, and you've

58:2 been in the field for a long time. If

58:3 you have a device on the market where its

58:4 risks exceed its benefits, in the

58:5 company's opinion, should you pull it

58:6 from the market?

58:7 A. You would -- your process

58:8 and procedures would pull it -- pull it

58:9 from the market. If -- if the risks

58:10 exceeded the benefit, you would do it

58:11 much quicker.

67:22 - 68:4

Shultz, Gin 01-30-2014 (00:00:16)

05_14_18 Jones Combo V3.7

67:22 Q. when you were at Bard

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67:23 as the vice president of quality
 67:24 assurance, was it your belief that
 68:1 customers had a right to be made aware of
 68:2 the risks that Bard was aware of
 68:3 regarding the devices?
 68:4 A. When we had an issue, yes.

68:24 - 69:2

Shultz, Gin 01-30-2014 (00:00:07)

05_14_18 Jones Combo V3.8

68:24 does a customer have the right to be made
 69:1 aware of the -- all known risks that the
 69:2 company is aware of regarding the device?

69:9 - 69:23

Shultz, Gin 01-30-2014 (00:00:43)

05_14_18 Jones Combo V3.9

69:9 A. Through our labeling, we
 69:10 will put -- we actually go through and we
 69:11 evaluate all of the risks. When we
 69:12 determine what the risks are, then we go
 69:13 in and look at what the normal use is on
 69:14 the device, or even misuse.
 69:15 And then we look at the
 69:16 labeling, and we look at what the
 69:17 indications, the contraindications, the
 69:18 warnings, and the precautions. And when
 69:19 we look at the risk management, anything
 69:20 that is important for the customer to
 69:21 know based on the general use of the
 69:22 device, we put that in the labeling.
 69:23 That's on the normal release.

71:21 - 71:24

Shultz, Gin 01-30-2014 (00:00:07)

05_14_18 Jones Combo V3.12

71:21 How do you identify what
 71:22 risks the company -- or customer has a
 71:23 right to be made aware of versus the
 71:24 others that you're not going to disclose?

72:6 - 72:20

Shultz, Gin 01-30-2014 (00:00:34)

05_14_18 Jones Combo V3.13

72:6 A. We'll disclose information
 72:7 to the customer.
 72:8 Q. Okay.
 72:9 A. The IFU, the training
 72:10 program, you need to give them the
 72:11 information so they know how to safely
 72:12 use the device and what to expect from
 72:13 the device and what they expect for

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72:14 complication rates.
 72:15 So within that process, we
 72:16 identify the function of the device and
 72:17 what's important for them to safely use
 72:18 the device. We don't send them the
 72:19 design portfolio for every device.
 72:20 They're not going to read it.

89:1 - 89:14

Shultz, Gin 01-30-2014 (00:00:37)

05_14_18 Jones Combo V3.19

89:1 And did you say the G2
 89:2 filter was cleared for use sometime in
 89:3 2005?
 89:4 A. The -- yes, it was -- it was
 89:5 cleared for permanent indication.
 89:6 Q. Okay. And the G2 filter was
 89:7 an extension of the Recovery filter with
 89:8 certain design modifications, right?
 89:9 A. Yes.
 89:10 Q. Okay. And it didn't get
 89:11 removal indication for about three years,
 89:12 right?
 89:13 A. I think it was 2009 it got
 89:14 the retrievable indication.

110:4 - 110:14

Shultz, Gin 01-30-2014 (00:00:21)

05_14_18 Jones Combo V3.27

110:4 Do you agree that a device
 110:5 that fractures can potentially cause
 110:6 injury?
 110:7 A. Yes.
 110:8 Q. Okay. Do you agree that a
 110:9 device that causes perforations can
 110:10 potentially cause injury?
 110:11 A. Yes.
 110:12 Q. Okay. So those are user
 110:13 needs in respect to safety, aren't they?
 110:14 A. Yes.

120:22 - 121:10

Shultz, Gin 01-30-2014 (00:00:18)

05_14_18 Jones Combo V3.29

120:22 Q. There is -- there is
 120:23 requirements that are required in design
 120:24 development --
 121:1 A. Yes.
 121:2 Q. -- to make sure this device

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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	121:3 is going to be safe and effective for its 121:4 intended use before you put it on the 121:5 market, right? 121:6 A. Yes. 121:7 Q. Okay. And it's never okay 121:8 for a manufacturer to skip those steps 121:9 and then say, "Well, we'll fix it once we 121:10 put it on the market," right?	
121:13 - 121:15	Shultz, Gin 01-30-2014 (00:00:03) 121:13 THE WITNESS: If it's a 121:14 safety issue, I agree with your 121:15 statement.	05_14_18 Jones Combo V3.30
123:21 - 124:3	Shultz, Gin 01-30-2014 (00:00:16) 123:21 if a manufacturer 123:22 becomes aware that one of its devices has 123:23 substantially higher failure rates than 123:24 its other devices that are used for the 124:1 same purpose, doesn't -- shouldn't the 124:2 manufacturer make consumers aware of 124:3 that?	05_14_18 Jones Combo V3.31
124:6 - 124:20	Shultz, Gin 01-30-2014 (00:00:38) 124:6 THE WITNESS: We're back to 124:7 the question around the 124:8 risk/benefit. 124:9 So if you have two devices, 124:10 and one has a much -- has a 124:11 greater benefit, there may be 124:12 applications to where you're going 124:13 to go with a potential failure 124:14 mode because the risk/benefit 124:15 analysis shows that it's a benefit 124:16 to have that product out in the 124:17 field. 124:18 It's part of what you look 124:19 at when -- even the FDA looks at 124:20 it on the approval of the devices.	05_14_18 Jones Combo V3.32
125:2 - 125:10	Shultz, Gin 01-30-2014 (00:00:14) 125:2 Q. Okay. So there's a couple 125:3 parts to that answer, and I want to 125:4 address them.	05_14_18 Jones Combo V3.33

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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	125:5 First is, it's --	
	125:6 ultimately, it's the physicians that	
	125:7 should be making the risk/benefit	
	125:8 decision about which device they are	
	125:9 going to use or not use, right?	
	125:10 A. Correct.	
125:11 - 125:16	Shultz, Gin 01-30-2014 (00:00:11)	05_14_18 Jones Combo V3.34
	125:11 Q. And they rely in part	
	125:12 on the manufacturer to give them a fair	
	125:13 and balanced disclosure of the risks and	
	125:14 benefits of the device so they can decide	
	125:15 which one to use or not use, right?	
	125:16 A. Correct.	
125:17 - 125:22	Shultz, Gin 01-30-2014 (00:00:14)	05_14_18 Jones Combo V3.35
	125:17 Q. Now, if two devices	
	125:18 had the same, exact intended use, and one	
	125:19 has substantially higher reported	
	125:20 failures than the other, is that	
	125:21 information that should be passed on to	
	125:22 the consumers?	
126:1 - 126:12	Shultz, Gin 01-30-2014 (00:00:30)	05_14_18 Jones Combo V3.36
	126:1 when we	
	126:2 have a clinical study, which is	
	126:3 prospective and you have good	
	126:4 comparison data, then that's the	
	126:5 type of information that you can	
	126:6 put into your labeling or	
	126:7 disclose, because then it's --	
	126:8 it's very clear what the data is	
	126:9 telling you.	
	126:10 So we have put that into our	
	126:11 labeling when we've had clinical	
	126:12 data.	
126:12 - 127:6	Shultz, Gin 01-30-2014 (00:00:42)	05_14_18 Jones Combo V3.37
	126:12 We've put in fracture rates	
	126:13 or migrate -- some rates in the	
	126:14 labeling.	
	126:15 When you look at the	
	126:16 complaint data, it's -- sometimes	
	126:17 when you get your complaint data,	

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126:18 you will file it with whatever
 126:19 it's alleged to. You may get the
 126:20 product back and find that the
 126:21 product isn't fractured or it
 126:22 doesn't have this issue.
 126:23 So the complaint data is
 126:24 confounded to some degree because
 127:1 it's not a scientific study that
 127:2 gives you clean data.
 127:3 So if you put that in your
 127:4 labeling, you're going to
 127:5 continually update it for whatever
 127:6 you find in your data.

127:8 - 127:17

Shultz, Gin 01-30-2014 (00:00:14)

05_14_18 Jones Combo V3.38

127:8 Q. So complaint data
 127:9 may -- may not be perfect, but it is a
 127:10 potential indicator that there is a
 127:11 design problem with the device, right?
 127:12
 127:13
 127:14 THE WITNESS: It could be.
 127:15 BY MR. BRENES:
 127:16 Q. It's a potential indicator?
 127:17 A. It's a potential indicator.

129:8 - 129:13

Shultz, Gin 01-30-2014 (00:00:16)

05_14_18 Jones Combo V3.39

129:8 If the complaint data shows
 129:9 that one of Bard's devices is being
 129:10 reported to fail substantially more than
 129:11 the other device, it is information that
 129:12 suggests that one device is safer than
 129:13 the other, right?

129:16 - 130:4

Shultz, Gin 01-30-2014 (00:00:21)

05_14_18 Jones Combo V3.40

129:16 all
 129:17 things -- all things being
 129:18 completely the same, if one -- if
 129:19 there's a failure rate more on one
 129:20 device than another and they do
 129:21 exactly the same thing, then the
 129:22 device that has the lower
 129:23 complaint rate would be a more

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	129:24 benign device.	
	130:1 BY MR. BRENES:	
	130:2 Q. And it is risk/benefit	
	130:3 information, right?	
	130:4 A. Yes, it is.	
139:14 - 139:17	Shultz, Gin 01-30-2014 (00:00:07)	05_14_18 Jones Combo V3.41
	139:14 In claiming a device as	
	139:15 predicate, Bard is claiming that the	
	139:16 Recovery filter is substantially similar	
	139:17 to the Simon Nitinol filter, isn't it?	
139:20 - 139:24	Shultz, Gin 01-30-2014 (00:00:06)	05_14_18 Jones Combo V3.42
	139:20 THE WITNESS: It's similar	
	139:21 in the function of the device.	
	139:22 It's similar in the safety and	
	139:23 efficacy. It's safety -- it's	
	139:24 similar in the technology.	
140:5 - 140:10	Shultz, Gin 01-30-2014 (00:00:13)	05_14_18 Jones Combo V3.43
	140:5 So as physicians who	
	140:6 previously used the Simon Nitinol filter	
	140:7 and now Bard is marketing the Recovery	
	140:8 filter, the presumption was the devices	
	140:9 had equivalent safety, right?	
	140:10 A. Yes.	
150:2 - 150:12	Shultz, Gin 01-30-2014 (00:00:26)	05_14_18 Jones Combo V3.44
	150:2 Q. did the	
	150:3 FDA have thresholds for failures? You	
	150:4 went on for a long time about that and	
	150:5 maybe some other things.	
	150:6 But are you representing	
	150:7 that the FDA adopted the SIR guidelines	
	150:8 as an acceptable threshold failure rate	
	150:9 for IVC filters?	
	150:10 A. At least in our meetings,	
	150:11 they acknowledged those rates and	
	150:12 compared against those rates	
168:8 - 168:10	Shultz, Gin 01-30-2014 (00:00:06)	05_14_18 Jones Combo V3.51
	168:8 Q. Do you agree that an	
	168:9 adulterated product is one that fails to	
	168:10 meet its minimum safety specifications?	
168:13 - 168:16	Shultz, Gin 01-30-2014 (00:00:04)	05_14_18 Jones Combo V3.52

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168:13 THE WITNESS: It's --

168:14 adulterated product would be

168:15 product that doesn't meet its

168:16 specification period.

168:18 - 169:8

Shultz, Gin 01-30-2014 (00:00:30)

05_14_18 Jones Combo V3.53

168:18 Q. Okay. And --

168:19 A. Of any sort.

168:20 Q. In this case, for the

168:21 filters, that would be migration

168:22 resistance specifications?

168:23 A. The --

168:24 Q. Among others?

169:1 A. It would be -- on

169:2 adulteration, it would be specifications

169:3 of the device. So there's not a release

169:4 test for releasing a batch from migration

169:5 resistance.

169:6 So the migration resistance

169:7 wouldn't be a specification on the

169:8 device.

175:2 - 175:9

Shultz, Gin 01-30-2014 (00:00:11)

05_14_18 Jones Combo V3.58

175:2 Q. Okay. So you have product

175:3 performance specifications that will lay

175:4 out what the specifications are?

175:5 A. Correct.

175:6 Q. Okay. So if the product

175:7 isn't meeting those specifications, then

175:8 it's adulterated?

175:9 A. Correct.

177:5 - 178:1

Shultz, Gin 01-30-2014 (00:00:28)

05_14_18 Jones Combo V3.59

177:5 Q. Okay. So as far as if

177:6 you become -- if Bard becomes concerned

177:7 about safety problems with the device --

177:8 A. Yes.

177:9 Q. -- and they want to get that

177:10 information out, there are measures Bard

177:11 can take?

177:12 A. Yes.

177:13 Q. Such as, they can do a field

177:14 correction, right?

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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	177:15 A. Yes.	
	177:16 Q. They can do a medical device	
	177:17 notification, right?	
	177:18 A. Yes.	
	177:19 Q. They can do a safety alert,	
	177:20 right?	
	177:21 A. Yes.	
	177:22 Q. They can do a recall?	
	177:23 A. Yes.	
	177:24 Q. Okay. Did Bard do any of	
	178:1 those with the Recovery filter?	
178:4 - 178:5	Shultz, Gin 01-30-2014 (00:00:02)	05_14_18 Jones Combo V3.60
	178:4 THE WITNESS: After -- after	
	178:5 I started with Bard, no.	
178:7 - 178:13	Shultz, Gin 01-30-2014 (00:00:13)	05_14_18 Jones Combo V3.61
	178:7 Q. Okay. Are you aware of them	
	178:8 doing any of those at any time?	
	178:9 A. I don't remember. I thought	
	178:10 they did.	
	178:11 Q. Okay. They sent out a Dear	
	178:12 Colleague letter? That may be --	
	178:13 A. That's what I was thinking.	
191:7 - 191:13	Shultz, Gin 01-30-2014 (00:00:12)	05_14_18 Jones Combo V3.62
	191:7 Q. Part of the reason of	
	191:8 looking at failure rates is try to figure	
	191:9 out if indeed yours has substantially	
	191:10 higher than other devices, if that is a	
	191:11 design issue with your product	
	191:12 responsible for that, right?	
	191:13 A. Correct.	
203:16 - 203:17	Shultz, Gin 01-30-2014 (00:00:02)	05_14_18 Jones Combo V3.63
	203:16 MR. BRENES: Mark this as	
	203:17 Exhibit Number 2.	
204:17 - 204:20	Shultz, Gin 01-30-2014 (00:00:08)	05_14_18 Jones Combo V3.64
	204:17 Q. Does this appear to be an	SCHULTZDEPOSITIONEXHIBITS-1253092.488.2
	204:18 e-mail from you to Micky Graves, Natalie	
	204:19 Wong and Brian Hudson?	
	204:20 A. Yes.	
206:3 - 206:7	Shultz, Gin 01-30-2014 (00:00:06)	05_14_18 Jones Combo V3.65
	206:3 Q. Is this likely when there	SCHULTZDEPOSITIONEXHIBITS-1253092.488

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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	206:4 started being reports for caudal 206:5 migration? Is that around the same time 206:6 frame? 206:7 A. Yes.	
206:15 - 206:22	Shultz, Gin 01-30-2014 (00:00:16) 206:15 Q. It says, "How do we compare 206:16 to SNF (permanent filters) on migration?" 206:17 Do you see that? 206:18 A. Yes, I do. 206:19 Q. So you were asking for a 206:20 comparison of the -- of presumably the G2 206:21 filter here, to the SNF, right? 206:22 A. Yes.	05_14_18 Jones Combo V3.66 SCHULTZDEPOSITIONEXHIBITS-123092488.3
207:24 - 208:19	Shultz, Gin 01-30-2014 (00:00:42) 207:24 Q. Okay. So do you agree that 208:1 this appears to be an e-mail from you 208:2 stating that you're going to use a 208:3 comparison of the safety profile of the 208:4 G2 filter versus that of the Simon 208:5 Nitinol filter in doing an analysis of 208:6 the risks and benefits of the G2 filter, 208:7 correct? 208:8 A. We're doing an evaluation of 208:9 data, and we are looking at comparison to 208:10 the Simon Nitinol, and we are looking at 208:11 the benefits to risk, yes. I don't know 208:12 what the data is though. 208:13 Q. And it says, "Determines 208:14 options as a company as the benefits to 208:15 risks may have changed." 208:16 A. Yes. 208:17 Q. And you're talking about the 208:18 G2 filter, right? 208:19 A. I'm assuming, yes.	05_14_18 Jones Combo V3.67 clear
210:12 - 210:19	Shultz, Gin 01-30-2014 (00:00:25) 210:12 Q. Is part of the reason Bard 210:13 was asking physicians about what their 210:14 expectations were for failure rates on 210:15 their devices was so that they would know 210:16 if further warnings were required?	05_14_18 Jones Combo V3.68 clear

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210:17 - 211:2	<p>210:17 A. The physician panel that I</p> <p>210:18 was talking to was on the G2, and it was</p> <p>210:19 talking to caudal migration.</p> <p>Shultz, Gin 01-30-2014 (00:00:16)</p> <p>210:20 Q. Okay. And that's fine.</p> <p>210:21 But -- so what's -- the next part of my</p> <p>210:22 question is, were you asking physicians</p> <p>210:23 about their expectations about failure</p> <p>210:24 rates so you would know, are you in line</p> <p>211:1 with those failures and whether further</p> <p>211:2 warnings were required?</p>	05_14_18 Jones Combo V3.69
211:5 - 211:15	<p>Shultz, Gin 01-30-2014 (00:00:23)</p> <p>211:5 THE WITNESS: The -- we were</p> <p>211:6 actually exploring -- it was a</p> <p>211:7 much broader question --</p> <p>211:8</p> <p>211:9 Q.</p> <p>211:10 A. -- is what are the</p> <p>211:11 implications of caudal migration? How</p> <p>211:12 does that affect the -- the treatment?</p> <p>211:13 Is this of a -- what's the severity of</p> <p>211:14 it? So we were actually exploring caudal</p> <p>211:15 migration in much broader terms.</p>	05_14_18 Jones Combo V3.70
217:15 - 217:20	<p>Shultz, Gin 01-30-2014 (00:00:08)</p> <p>217:15 Q. And then the next</p> <p>217:16 bullet point, same section, "A filter</p> <p>217:17 should not migrate no matter what the</p> <p>217:18 size of the thrombus burden it captures."</p> <p>217:19 Do you see that?</p> <p>217:20 A. Yes, I do.</p>	05_14_18 Jones Combo V3.71
217:21 - 218:4	<p>Shultz, Gin 01-30-2014 (00:00:20)</p> <p>217:21 Q. When you were head of</p> <p>217:22 quality, deciding, you know, what</p> <p>217:23 additional warnings needed to be given or</p> <p>217:24 if corrective action needed to be taken,</p> <p>218:1 were you taking into account this</p> <p>218:2 physician feedback that had told Bard,</p> <p>218:3 "No matter what the size of a thrombus,</p> <p>218:4 filters shouldn't migrate"?</p>	05_14_18 Jones Combo V3.72
218:7 - 218:19	<p>Shultz, Gin 01-30-2014 (00:00:38)</p>	05_14_18 Jones Combo V3.73

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	218:7 THE WITNESS: The -- that is	
	218:8 part of the feedback. That is the	
	218:9 design, what we'd want the filter	
	218:10 to do. So that would be	
	218:11 considered.	
	218:12 The fact that the filters	
	218:13 took the recurring PE rate down to	
	218:14 such a low level showed that the	
	218:15 filter did a substantial job or	
	218:16 function in eliminating the	
	218:17 migration, the PEs.	
	218:18 So this is -- that is the --	
	218:19 that is the intent of the filter.	
226:16 - 226:16	Shultz, Gin 01-30-2014 (00:00:01)	05_14_18 Jones Combo V3.78
	226:16 Exhibit Number 4.	SCHULTZDEPOSITIONEXHIBITS-1253092.506
227:4 - 227:13	Shultz, Gin 01-30-2014 (00:00:15)	05_14_18 Jones Combo V3.79
	227:4 Ms. Schulz, you mentioned	
	227:5 there was another physician panel in	
	227:6 2006; is that right?	SCHULTZDEPOSITIONEXHIBITS-1253092.506.8
	227:7 A. There was a physician panel	
	227:8 that I was involved with. This is -- I'm	
	227:9 looking at it now. It might be the one	
	227:10 that I was involved in.	
	227:11 Q. Does it appear to be this	
	227:12 one?	
	227:13 A. I think so.	
227:23 - 228:2	Shultz, Gin 01-30-2014 (00:00:05)	05_14_18 Jones Combo V3.80
	227:23 Q. Have you seen this	clear
	227:24 document before?	
	228:1 A. Actually, I'm not sure I	
	228:2 have.	
228:10 - 228:19	Shultz, Gin 01-30-2014 (00:00:13)	05_14_18 Jones Combo V3.81
	228:10 Q. Do you see where it says,	SCHULTZDEPOSITIONEXHIBITS-1253092.506.2
	228:11 "Expect as close as possible to zero -	
	228:12 everyone."	
	228:13 Do you see that?	
	228:14 A. Yes.	
	228:15 Q. So do you agree that all the	
	228:16 physicians were saying you should try to	
	228:17 get a device that has zero fracture rate,	

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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	228:18 if possible?	
	228:19 A. Yes.	
228:20 - 228:24	Shultz, Gin 01-30-2014 (00:00:05)	05_14_18 Jones Combo V3.82
	228:20 Q. So in other words,	clear
	228:21 like we said earlier, make the device --	
	228:22 manufacturers should make the device as	
	228:23 safe as possible?	
	228:24 A. Yes.	
275:21 - 275:22	Shultz, Gin 01-30-2014 (00:00:02)	05_14_18 Jones Combo V3.83
	275:21 Q. I'll hand you what's	
	275:22 Exhibit 5.	
279:5 - 279:10	Shultz, Gin 01-30-2014 (00:00:10)	05_14_18 Jones Combo V3.84
	279:5 Q. Were you told that	
	279:6 there was a problem with filter fracture	
	279:7 with the Recovery filter?	
	279:8 A. Yes.	
	279:9 Q. And that the G2 filter was	
	279:10 to fix those problems?	
279:14 - 279:21	Shultz, Gin 01-30-2014 (00:00:23)	05_14_18 Jones Combo V3.85
	279:14 Q. That was the purpose?	
	279:15 A. No. I was told that the --	
	279:16 there was complaint rates for the --	
	279:17 there was an investigation. I read the	
	279:18 investigation. It was redesigned. G2	
	279:19 was the launch on that.	
	279:20 Q. Okay. To fix the problem	
	279:21 with migration and fractures, right?	
279:24 - 280:2	Shultz, Gin 01-30-2014 (00:00:07)	05_14_18 Jones Combo V3.86
	279:24 THE WITNESS: It was --	
	280:1 yeah, to address, minimize filter	
	280:2 migration, fracture.	
280:4 - 280:6	Shultz, Gin 01-30-2014 (00:00:03)	05_14_18 Jones Combo V3.87
	280:4 Q. And this e-mail I	
	280:5 handed to you that we marked as Exhibit	
	280:6 Number 6,	
281:24 - 282:1	Shultz, Gin 01-30-2014 (00:00:03)	05_14_18 Jones Combo V3.88
	281:24 Q. I'll hand you what we'll	
	282:1 mark as Exhibit Number 7.	
282:19 - 283:5	Shultz, Gin 01-30-2014 (00:00:27)	05_14_18 Jones Combo V3.89
	282:19 Q. What is a health	

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	282:20 hazard evaluation, according to your 282:21 understanding from your time at Bard? 282:22 A. It's where we evaluate a 282:23 failure mode or a nonconformance. It's 282:24 in the field against the potential 283:1 hazards. 283:2 Q. Is it in essence a 283:3 risk/benefit analysis? 283:4 A. It's the -- it's a portion 283:5 of it, yes.	
301:11 - 301:15	Shultz, Gin 01-30-2014 (00:00:15) 301:11 Q. Okay. So do you agree or 301:12 disagree that statistically significant 301:13 higher rates of reported failures between 301:14 devices is an important safety signal? 301:15 A. Yes.	05_14_18 Jones Combo V3.90
301:19 - 301:20	Shultz, Gin 01-30-2014 (00:00:02) 301:19 Q. You agree to that? 301:20 A. Yes.	05_14_18 Jones Combo V3.91
343:12 - 343:15	Shultz, Gin 01-30-2014 (00:00:02) 343:12 MR. BRENES: We're going to 343:13 mark what -- hand you what we're 343:14 going to mark as Exhibit Number 343:15 11.	05_14_18 Jones Combo V3.92 SCHULTZDEPOSITIONEXHIBITS-1253692.548
343:23 - 344:15	Shultz, Gin 01-30-2014 (00:00:37) 343:23 Q. Are you familiar with 343:24 documents like this from your time at 344:1 Bard? 344:2 A. Yes. 344:3 Q. And what does it appear to 344:4 be? 344:5 A. It's a comparison by 344:6 complaint type of different filters. 344:7 Q. And this was used to track 344:8 competitive -- competitive failure rates 344:9 between different devices? 344:10 A. Yeah, to evaluate rates 344:11 across the board. 344:12 Q. And to determine if there 344:13 was a safety issue with one of Bard's	05_14_18 Jones Combo V3.93 clear

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344:24 - 345:21	<p>344:14 devices, right?</p> <p>344:15 A. Yes.</p> <p>Shultz, Gin 01-30-2014 (00:00:59)</p> <p>344:24 Do you see towards the</p> <p>345:1 bottom of the first page, it says, "Bard</p> <p>345:2 data is from Trackwise, not MAUDE,</p> <p>345:3 through July 2010."</p> <p>345:4 Do you see that?</p> <p>345:5 A. Yes.</p> <p>345:6 Q. Okay. And Trackwise was</p> <p>345:7 Bard's internal complaint tracking</p> <p>345:8 system, right?</p> <p>345:9 A. Yes.</p> <p>345:10 Q. Okay. So this is through</p> <p>345:11 July of 2010.</p> <p>345:12 So as of July of 2010,</p> <p>345:13 there's 179 reported fractures for the</p> <p>345:14 Recovery filter, right?</p> <p>345:15 A. Correct.</p> <p>345:16 Q. Okay. And if we compare</p> <p>345:17 that to that last memorandum from</p> <p>345:18 November '05, you're looking at over an</p> <p>345:19 additional 120 fractures since that time,</p> <p>345:20 right?</p> <p>345:21 A. Roughly. Yes.</p>	<p>05_14_18 Jones Combo V3.94</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.548.1</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.548.3</p> <p>clear</p>
346:4 - 346:11	<p>Shultz, Gin 01-30-2014 (00:00:15)</p> <p>346:4 THE WITNESS: The number is</p> <p>346:5 95. I'm sorry. The difference</p> <p>346:6 between the two, right?</p> <p>346:7 BY MR. BRENES:</p> <p>346:8 Q. 179 minus --</p> <p>346:9 A. 84.</p> <p>346:10 Q. Oh, you're right. Yeah.</p> <p>346:11 Good point.</p>	<p>05_14_18 Jones Combo V3.95</p>
346:24 - 347:9	<p>Shultz, Gin 01-30-2014 (00:00:23)</p> <p>346:24 Q. Did Bard ever discuss or try</p> <p>347:1 to figure out how many additional</p> <p>347:2 fractures there likely would be in</p> <p>347:3 deciding whether or not to take the</p> <p>347:4 device off the market or do a recall for</p>	<p>05_14_18 Jones Combo V3.96</p>

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	347:5 the device?	
	347:6 A. There wasn't, to my memory,	
	347:7 a prediction or projection of how many	
	347:8 fractures would be out there before you	
	347:9 would react to that.	
347:10 - 347:16	Shultz, Gin 01-30-2014 (00:00:16)	05_14_18 Jones Combo V3.97
	347:10 Q. If Bard did do such a	
	347:11 prediction, and then, in fact, the	
	347:12 fracture rate exceeded what had been	
	347:13 predicted, future fracture rate exceeded	
	347:14 what had been predicted, would that have	
	347:15 prompted further warnings from Bard to	
	347:16 physicians?	
347:19 - 347:19	Shultz, Gin 01-30-2014 (00:00:01)	05_14_18 Jones Combo V3.98
	347:19 THE WITNESS: It could have.	
352:22 - 353:5	Shultz, Gin 01-30-2014 (00:00:18)	05_14_18 Jones Combo V3.99
	352:22 Q. No. And then looking at the	
	352:23 G2, the G2 has a reported migration rate	
	352:24 of 1.2 out of every thousand, right?	
	353:1 A. Yes.	
	353:2 Q. Okay. And is any device,	
	353:3 other than a Bard device, even close to	
	353:4 that migration rate?	
	353:5 A. No.	
357:11 - 357:12	Shultz, Gin 01-30-2014 (00:00:02)	05_14_18 Jones Combo V3.100
	357:11 Q. Let's mark this as	SCHULTZDEPOSITIONEXHIBITS-1253092.558
	357:12 Exhibit 12.	
357:19 - 357:22	Shultz, Gin 01-30-2014 (00:00:09)	05_14_18 Jones Combo V3.101
	357:19 Q. Do you agree this appears to	SCHULTZDEPOSITIONEXHIBITS-1253092.559.6
	357:20 be an e-mail from Kelly Jones to you	
	357:21 dated November 30th, 2005?	
	357:22 A. Yes.	
363:7 - 363:13	Shultz, Gin 01-30-2014 (00:00:17)	05_14_18 Jones Combo V3.102
	363:7 Q. So you agree, again, the	clear
	363:8 Recovery filter's failure rates for	
	363:9 migration, death, fracture, pulmonary	
	363:10 embolism, perforation, are all	
	363:11 substantially higher than the SNF,	
	363:12 correct?	
	363:13 A. Yes.	

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Page/Line	Source	ID
378:5 - 378:10	Shultz, Gin 01-30-2014 (00:00:16) 378:5 Q. Okay. I'm going to hand you 378:6 what we'll mark as Exhibit Number -- 378:7 A. 15. 378:8 Q. -- 15. I'm going to hand 378:9 you the e-mail and the attachment that 378:10 went with it. There you go.	05_14_18 Jones Combo V3.103 SCHULTZDEPOSITIONEXHIBITS-1253092.559
378:19 - 379:2	Shultz, Gin 01-30-2014 (00:00:22) 378:19 Q. Please take a minute to 378:20 review it. There's also an attachment 378:21 for caudal migration, which I didn't give 378:22 you. I just want to talk about fractures 378:23 right now. You know what? Let's make it 378:24 complete. I'm going to give you the 379:1 caudal migration attachment as well just 379:2 so you have all the attachments.	05_14_18 Jones Combo V3.104 clear
379:19 - 380:3	Shultz, Gin 01-30-2014 (00:00:25) 379:19 Q. So do you see the e-mail, 379:20 which is from Natalie Wong to you among 379:21 some others dated May 19th, 2006? 379:22 A. Yes. 379:23 Q. Okay. And the -- I don't 379:24 see a subject, but the attachments are 380:1 "G2 caudal summary," and "RNF fracture 380:2 report." Right? 380:3 A. Yes.	05_14_18 Jones Combo V3.105 SCHULTZDEPOSITIONEXHIBITS-1253092.559 SCHULTZDEPOSITIONEXHIBITS-1253092.559.3
385:5 - 385:22	Shultz, Gin 01-30-2014 (00:00:49) 385:5 Q. Okay. And does it appear 385:6 that Bard is contemplating some 385:7 additional corrective action regarding 385:8 the Recovery filter in this PowerPoint? 385:9 A. Yes. 385:10 Q. And one of those things is 385:11 potentially a customer letter, right? 385:12 A. Yes. 385:13 Q. Okay. Content, it says, 385:14 "Notify fracture rate. Standard of care 385:15 applies, risk/benefit compared to 385:16 competitors." 385:17 Do you see that?	05_14_18 Jones Combo V3.106 SCHULTZDEPOSITIONEXHIBITS-1253092.602.1 SCHULTZDEPOSITIONEXHIBITS-1253092.602.3

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	385:18 A. Yes.	
	385:19 Q. So it appears to be	
	385:20 contemplating the potential disclosure of	
	385:21 competitive fracture rates so doctors can	
	385:22 do risk/benefit analysis, right?	
386:1 - 386:15	Shultz, Gin 01-30-2014 (00:00:19)	05_14_18 Jones Combo V3.107
	386:1 THE WITNESS: For the	
	386:2 content, the risk/benefit was that	
	386:3 we would provide the risk/benefit	
	386:4 and compare to competitors. What	
	386:5 they do with it was something	
	386:6 else.	clear
	386:7 BY MR. BRENES:	
	386:8 Q. Got it. So in other words	
	386:9 you could -- providing your analysis of	
	386:10 what the risks and the benefits are of	
	386:11 the filter --	
	386:12 A. Right.	
	386:13 Q. -- in respect to competitive	
	386:14 failure rates?	
	386:15 A. Yes.	
387:19 - 388:1	Shultz, Gin 01-30-2014 (00:00:12)	05_14_18 Jones Combo V3.108
	387:19 Q. Now, in fairness let's look	
	387:20 at the cons. "Does not provide	
	387:21 additional information that physician	
	387:22 does not already know."	
	387:23 Do you see that? Do you see	
	387:24 that?	
	388:1 A. Yes, I do.	
388:2 - 388:16	Shultz, Gin 01-30-2014 (00:00:32)	05_14_18 Jones Combo V3.109
	388:2 Q. Okay. Now, physicians don't	
	388:3 know -- don't necessarily know what	
	388:4 Bard's complaint files reveal, right?	
	388:5 A. Correct. They don't have	
	388:6 specific information on the complaint	
	388:7 files.	
	388:8 Q. And they -- and Bard never	
	388:9 provided them with competitive failure	
	388:10 rate information, right, as far as you	
	388:11 know?	

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	388:12 A. As far as I know.	
	388:13 Q. And you would certainly	
	388:14 agree that Bard's own complaint files and	
	388:15 sales rate information is more reliable	
	388:16 than general MAUDE data, right?	
388:19 - 388:21	Shultz, Gin 01-30-2014 (00:00:05)	05_14_18 Jones Combo V3.110
	388:19 THE WITNESS: Bard's	
	388:20 complaint data is more accurate	
	388:21 than the MAUDE database.	
388:23 - 389:19	Shultz, Gin 01-30-2014 (00:00:54)	05_14_18 Jones Combo V3.111
	388:23 Q. The second con is,	
	388:24 "Notifying patients that may never have	
	389:1 complications."	
	389:2 Do you know what they mean	
	389:3 by that?	
	389:4 A. So the -- in some of the	
	389:5 data analysis, the majority of the	
	389:6 patients were asymptomatic for fractures.	
	389:7 And so when they -- similar to the issue	
	389:8 with monitoring for breast cancer, that	
	389:9 people will have false negative, so they	
	389:10 start reacting, and they have additional	
	389:11 healthcare. It causes additional issues.	
	389:12 So, you know, the fact that	
	389:13 most of the patients were asymptomatic	
	389:14 and the fact that they start notifying	
	389:15 them, then you're going to have patients	
	389:16 trying to figure out what that means or	
	389:17 not means and that type of issue --	
	389:18 Q. Okay.	
	389:19 A. -- is more of that line.	
394:15 - 394:23	Shultz, Gin 01-30-2014 (00:00:19)	05_14_18 Jones Combo V3.112
	394:15 Q. Okay. Go to the next page,	
	394:16 "Potential next steps," and, "Recall	SCHULTZDEPOSITIONEXHIBITS-1253892.603.11
	394:17 existing inventory." Do you see that?	
	394:18 A. Yes.	
	394:19 Q. So it appears Bard was	
	394:20 contemplating the possibility of	
	394:21 recalling the Recovery filter, even in	
	394:22 '06, right?	

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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394:24 - 395:2	<p>394:23 A. Yes.</p> <p>Shultz, Gin 01-30-2014 (00:00:05)</p> <p>394:24 Q. Okay. The pro is, "Update 395:1 inventory with better performing filter," 395:2 right?</p>	<p>05_14_18 Jones Combo V3.113</p> <p>clear</p>
395:3 - 395:3	<p>Shultz, Gin 01-30-2014 (00:00:01)</p> <p>395:3 A. Yes.</p>	05_14_18 Jones Combo V3.114
395:4 - 395:7	<p>Shultz, Gin 01-30-2014 (00:00:07)</p> <p>395:4 Q. Shouldn't that be a 395:5 company's goal, is always get a patient 395:6 the best and the safest device a company 395:7 has?</p>	05_14_18 Jones Combo V3.115
395:10 - 395:18	<p>Shultz, Gin 01-30-2014 (00:00:13)</p> <p>395:10 THE WITNESS: That -- 395:11 that's -- if you look at the 395:12 iterations of the filter, that is 395:13 the desire of the product all the 395:14 way through. 395:15 BY MR. BRENES: 395:16 Q. Okay. 395:17 A. We've -- the performance has 395:18 improved with every iteration.</p>	05_14_18 Jones Combo V3.116
399:21 - 400:9	<p>Shultz, Gin 01-30-2014 (00:00:20)</p> <p>399:21 Bard didn't recall the 399:22 Recovery filter, correct? 399:23 A. Correct. 399:24 Q. Bard didn't suggest that 400:1 physicians explant the Recovery filter, 400:2 correct? 400:3 A. Correct. 400:4 Q. And they basically took 400:5 Option 3, which was no field action -- 400:6 A. Correct. 400:7 Q. -- regarding the Recovery 400:8 filter, correct? 400:9 A. Correct.</p>	05_14_18 Jones Combo V3.121
415:22 - 416:2	<p>Shultz, Gin 01-30-2014 (00:00:10)</p> <p>415:22 Q. Simply, did -- are you aware 415:23 of Bard -- whether or not Bard shared 415:24 information with the doctors about the</p>	05_14_18 Jones Combo V3.146

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Page/Line	Source	ID
416:6 - 416:7	<p>416:1 comparative failure rates between Simon 416:2 Nitinol filter and the G2 filter? Shultz, Gin 01-30-2014 (00:00:01) 416:6 THE WITNESS: Not to my 416:7 knowledge.</p>	05_14_18 Jones Combo V3.147
417:9 - 417:11	<p>Shultz, Gin 01-30-2014 (00:00:04) 417:9 Q. Okay. So at some point, did 417:10 you become aware that there were 417:11 stability problems with the G2 filter?</p>	05_14_18 Jones Combo V3.148
417:14 - 418:3	<p>Shultz, Gin 01-30-2014 (00:00:25) 417:14 THE WITNESS: The G2 filter 417:15 on launch, we monitored migration, 417:16 and that's where we identified 417:17 caudal migration. 417:18 BY MR. BRENES: 417:19 Q. And did you also become 417:20 aware that there were problems with the 417:21 device tilting? 417:22 A. There was complaints of it 417:23 tilting as well. 417:24 Q. Okay. And did you also 418:1 become aware of fracture rates that were 418:2 higher than for the Simon Nitinol filter 418:3 for the G2 filter?</p>	05_14_18 Jones Combo V3.149
418:6 - 418:17	<p>Shultz, Gin 01-30-2014 (00:00:14) 418:6 THE WITNESS: We monitored 418:7 the fracture rates. 418:8 BY MR. BRENES: 418:9 Q. And those were higher with 418:10 the G2 filter than with the Simon Nitinol 418:11 filter, correct? 418:12 A. Yes. We've gone through the 418:13 exhibits. Yes. 418:14 Q. And the migration rates were 418:15 higher for the G2 filter than the Simon 418:16 Nitinol filter, correct? 418:17 A. Yes.</p>	05_14_18 Jones Combo V3.150
422:18 - 422:21	<p>Shultz, Gin 01-30-2014 (00:00:08) 422:18 Now, in respect to G2, are 422:19 you aware that the G2 was being</p>	05_14_18 Jones Combo V3.158

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422:24 - 423:2	<p>422:20 redesigned because of the caudal 422:21 migration problem?</p> <p>Shultz, Gin 01-30-2014 (00:00:03)</p> <p>422:24 THE WITNESS: The G2 was 423:1 being redesigned, and we were 423:2 looking at caudal migration.</p>	05_14_18 Jones Combo V3.159
431:14 - 431:17	<p>Shultz, Gin 01-30-2014 (00:00:11)</p> <p>431:14 Q. Okay. Did Bard send a 431:15 customer letter notifying physicians that 431:16 there was an unexpected level of reported 431:17 caudal migrations?</p>	05_14_18 Jones Combo V3.160
431:20 - 431:20	<p>Shultz, Gin 01-30-2014 (00:00:00)</p> <p>431:20 THE WITNESS: No.</p>	05_14_18 Jones Combo V3.161
431:22 - 432:5	<p>Shultz, Gin 01-30-2014 (00:00:20)</p> <p>431:22 Q. And are you aware of a 431:23 communication from Dr. Ciavarella in 2006 431:24 asking why Bard is even selling the G2 432:1 filter when there's another permanent 432:2 filter, the Simon Nitinol filter, with 432:3 virtually no complaints? 432:4 A. That is actually a document 432:5 that we did look at.</p>	05_14_18 Jones Combo V3.162
432:13 - 432:14	<p>Shultz, Gin 01-30-2014 (00:00:03)</p> <p>432:13 Q. Okay. And what do you have 432:14 to say about that e-mail?</p>	05_14_18 Jones Combo V3.163
433:1 - 433:4	<p>Shultz, Gin 01-30-2014 (00:00:07)</p> <p>433:1 THE WITNESS: Dr. Ciavarella 433:2 wasn't at the division. He didn't 433:3 understand a lot of the details of 433:4 it.</p>	05_14_18 Jones Combo V3.164
434:19 - 434:20	<p>Shultz, Gin 01-30-2014 (00:00:03)</p> <p>434:19 MR. BRENES: We're going to 434:20 mark this as Exhibit Number 17.</p>	05_14_18 Jones Combo V3.165 SCHULTZDEPOSITIONEXHIBITS-1253092.642
435:4 - 436:5	<p>Shultz, Gin 01-30-2014 (00:01:01)</p> <p>435:4 Q. Okay. And this appears to 435:5 be a document or an e-mail from you to a 435:6 number of people at Bard, right? 435:7 A. Yes. 435:8 Q. And it appears to be 435:9 discussing caudal migrations with the G2</p>	05_14_18 Jones Combo V3.166 SCHULTZDEPOSITIONEXHIBITS-1253092.642.1 SCHULTZDEPOSITIONEXHIBITS-1253092.642.2

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435:10 filter, correct?

435:11 A. Yes.

435:12 Q. Okay. The first page under

435:13 "discussion points," do you see the

435:14 bullet point -- I think it's Number 3.

435:15 It says, "Project approved to redesign

435:16 and develop caudal movement test method."

435:17 Do you see that?

435:18 A. Yes.

435:19 Q. Okay. So does this refresh

435:20 your recollection as to whether or not

435:21 there was a test for caudal migration

435:22 before the G2 filter went on the market?

435:23 A. The -- so there was a test

435:24 method for caudal migration that needed

436:1 to be made.

436:2 Q. Okay. So there wasn't one

436:3 before?

436:4 A. There -- there may not have

436:5 been, or it may not have been adequate.

440:4 - 440:5

Shultz, Gin 01-30-2014 (00:00:02)

440:4 Q. I'm going to hand you what

440:5 we'll mark as Exhibit 19. Please take a

440:12 - 440:23

Shultz, Gin 01-30-2014 (00:00:26)

440:12 Q. So do you agree that it

440:13 appears to be an e-mail dated May 10,

440:14 2006, between Bard personnel regarding a

440:15 proposed response to FDA questions

440:16 regarding a complaint?

440:17 A. It's in response to an FDA

440:18 question -- yeah, it's about a complaint:

440:19 It's got a manufacturing report number.

440:20 Q. Okay. And the e-mail is

440:21 dated -- I may have said this -- is dated

440:22 May 10, 2006, right?

440:23 A. Yes.

441:5 - 442:2

Shultz, Gin 01-30-2014 (00:00:51)

441:5 Q. It says, "As defined in the

441:6 design failure modes and effects analysis

441:7 (DFMEA) for this product, the expected

SCHULTZDEPOSITIONEXHIBITS-1253092.642.3

clear

05_14_18 Jones Combo V3.167

SCHULTZDEPOSITIONEXHIBITS-1253092.647

05_14_18 Jones Combo V3.168

SCHULTZDEPOSITIONEXHIBITS-1253092.647.1

05_14_18 Jones Combo V3.169

SCHULTZDEPOSITIONEXHIBITS-1253092.648.3

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441:8 frequency of occurrence for caudal
 441:9 migration is less than or equal to
 441:10 0.05 percent."
 441:11 A. Yes.
 441:12 Q. Okay. And that is five out
 441:13 of every 10,000?
 441:14 A. Yes.
 441:15 Q. And then it continues, "The
 441:16 observed frequency of occurrence is
 441:17 .129 percent, as of April 30, 2006,"
 441:18 right?
 441:19 A. Correct.
 441:20 Q. Okay. And that -- so that's
 441:21 1.2 out of every thousand, right?
 441:22 A. Correct.
 441:23 Q. Okay. So we agree that
 441:24 caudal migration had exceeded Bard's
 442:1 expected occurrence levels?
 442:2 A. Correct.

442:6 - 442:14

Shultz, Gin 01-30-2014 (00:00:20)

05_14_18 Jones Combo V3.170

SCHULTZDEPOSITIONEXHIBITS-
1253092.650.2

442:6 Q. Exhibit Number 20, again,
 442:7 just because of time concerns, let me
 442:8 address some specific things.
 442:9 So does this appear to be an
 442:10 e-mail from Tracy Estrada, dated
 442:11 April 1st, 2010, to some other people at
 442:12 Bard with an attachment, "Eclipse Anchor
 442:13 Idea POA Final," right?
 442:14 A. Yes.

444:7 - 444:15

Shultz, Gin 01-30-2014 (00:00:14)

05_14_18 Jones Combo V3.171

SCHULTZDEPOSITIONEXHIBITS-
1253092.652.1

444:7 Q. Look under -- actually,
 444:8 "situation." Do you see where it says,
 444:9 "Physician perception is that design
 444:10 sacrifices were made to optional filters
 444:11 that permit retrievability, but also
 444:12 allow for a higher rate of movement or
 444:13 migration."
 444:14 Do you see that?
 444:15 A. Yes.

445:17 - 446:1

Shultz, Gin 01-30-2014 (00:00:22)

05_14_18 Jones Combo V3.172

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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	445:17 Q. Either from speaking with 445:18 physicians, from doing surveys, what have 445:19 you? 445:20 A. I don't -- I don't ever 445:21 remember a physician have a perception of 445:22 that. But I do know that there was 445:23 differences in the way a retrievable or 445:24 optional filter would perform than a 446:1 permanent filter.	clear
446:14 - 447:6	Shultz, Gin 01-30-2014 (00:00:30) 446:14 Q. Okay. Look at "problems" 446:15 for me, where it says, "Filter movement 446:16 may lead to tilting, undesirable cava 446:17 wall incorporation, increased risk of 446:18 filter fracture and vena cava 446:19 penetration." 446:20 Do you see that? 446:21 A. Yes. 446:22 Q. Is that consistent with your 446:23 understanding that movement may lead to 446:24 tilting? 447:1 A. Yes. That was a hypothesis, 447:2 that the movement would cause the 447:3 tilting. 447:4 Q. Was it consistent with your 447:5 understanding that movement could lead to 447:6 penetration into the vena cava?	05_14_18 Jones Combo V3.173 SCHULTZDEPOSITIONEXHIBITS- 1230922622
447:9 - 447:19	Shultz, Gin 01-30-2014 (00:00:22) 447:9 THE WITNESS: It was my 447:10 understanding that tilting could 447:11 lead to penetration. 447:12 BY MR. BRENES: 447:13 Q. Okay. And was it your 447:14 understanding that movement could lead to 447:15 filter fracture? 447:16 A. More back to the tilted, 447:17 that if you had a tilted filter, then 447:18 you're going to have uneven stresses on 447:19 it. And that would lead to it.	clear 05_14_18 Jones Combo V3.174
448:7 - 448:8	Shultz, Gin 01-30-2014 (00:00:02)	05_14_18 Jones Combo V3.175

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

Page/Line	Source	ID
448:7 - 448:13	<p>448:7 A. That that was a potential</p> <p>448:8 contributor to it.</p> <p>Shultz, Gin 01-30-2014 (00:00:10)</p> <p>448:9 Q. So maybe the better</p> <p>448:10 way to ask it is, was it your</p> <p>448:11 understanding that tilting could lead to</p> <p>448:12 increased risk of perforation and</p> <p>448:13 fracture?</p>	05_14_18 Jones Combo V3.176
448:16 - 448:18	<p>Shultz, Gin 01-30-2014 (00:00:04)</p> <p>448:16 THE WITNESS: Yes.</p> <p>448:17 BY MR. BRENES:</p> <p>448:18 Q. Yes to both?</p>	05_14_18 Jones Combo V3.177
448:21 - 449:18	<p>Shultz, Gin 01-30-2014 (00:00:42)</p> <p>448:21 THE WITNESS: Yes.</p> <p>448:22 BY MR. BRENES:</p> <p>448:23 Q. Okay. Look under</p> <p>448:24 "hypothesis," where it says, "The</p> <p>449:1 addition of caudal anchors to Eclipse</p> <p>449:2 filters will reduce caudal migrations."</p> <p>449:3 Do you see that?</p> <p>449:4 A. Yes.</p> <p>449:5 Q. Okay. "Reduce complaints</p> <p>449:6 for tilt," do you see that?</p> <p>449:7 A. Yes.</p> <p>449:8 Q. "Reduce complaints for</p> <p>449:9 fracture," do you see that?</p> <p>449:10 A. "Reduce complaints for tilt,</p> <p>449:11 fracture and penetration."</p> <p>449:12 Q. Okay. Secondary to -- here</p> <p>449:13 it says caudal migration, right?</p> <p>449:14 A. Yes.</p> <p>449:15 Q. But the main thing was</p> <p>449:16 reduce the incidence, in your mind of</p> <p>449:17 tilting, which then would -- could</p> <p>449:18 potentially lead to those issues, right?</p>	<p>05_14_18 Jones Combo V3.178</p> <p>SCHULTZDEPOSITIONEXHIBITS-1233092.652.3</p> <p>SCHULTZDEPOSITIONEXHIBITS-1233092.653.1</p>
449:21 - 449:23	<p>Shultz, Gin 01-30-2014 (00:00:07)</p> <p>449:21 THE WITNESS: The tilt to me</p> <p>449:22 was more significant than the</p> <p>449:23 caudal.</p>	05_14_18 Jones Combo V3.179
450:9 - 450:20	<p>Shultz, Gin 01-30-2014 (00:00:33)</p>	05_14_18 Jones Combo V3.180

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	<p>450:9 Q. Yeah. Look for me on the</p> <p>450:10 page ending in 860 under "strategic</p> <p>450:11 rationale." Second sentence, do you see</p> <p>450:12 where it says, "Eclipse with caudal</p> <p>450:13 anchors would be positioned as the</p> <p>450:14 premier optional filter with existing and</p> <p>450:15 new customers, infuse enthusiasm for the</p> <p>450:16 product into the sales team, and address</p> <p>450:17 quality issues with the predicate filter</p> <p>450:18 products."</p> <p>450:19 Do you see that?</p> <p>450:20 A. Yes.</p>	<p>SCHULTZDEPOSITIONEXHIBITS-1253092.654.1</p>
451:16 - 452:1	<p>Shultz, Gin 01-30-2014 (00:00:26)</p> <p>451:16 Q. Continuing, "The performance</p> <p>451:17 issues of BPV optional filters have led</p> <p>451:18 to sales attrition, and these</p> <p>451:19 complications overshadow the unique</p> <p>451:20 long-term retrievability of these</p> <p>451:21 products."</p> <p>451:22 Were you aware in this time</p> <p>451:23 frame, April 2010, that the performance</p> <p>451:24 issues with the -- Bard's filters was</p> <p>452:1 leading to sales attrition?</p>	<p>05_14_18 Jones Combo V3.181</p> <p>SCHULTZDEPOSITIONEXHIBITS-1253092.654.2</p>
452:4 - 452:13	<p>Shultz, Gin 01-30-2014 (00:00:27)</p> <p>452:4 THE WITNESS: There was a --</p> <p>452:5 across the industry, of the filter</p> <p>452:6 product lines, the sales were</p> <p>452:7 either not growing at the rate or</p> <p>452:8 growing at a slower rate or</p> <p>452:9 staying flat.</p> <p>452:10 And there was general</p> <p>452:11 communications across many</p> <p>452:12 regulatory industries around</p> <p>452:13 filters.</p>	<p>05_14_18 Jones Combo V3.182</p> <p>clear</p>
452:15 - 452:18	<p>Shultz, Gin 01-30-2014 (00:00:05)</p> <p>452:15 Q. This isn't talking about</p> <p>452:16 other people's products. This is talking</p> <p>452:17 about Bard's products, right?</p> <p>452:18 A. Yep.</p>	<p>05_14_18 Jones Combo V3.183</p>
453:8 - 453:13	<p>Shultz, Gin 01-30-2014 (00:00:09)</p>	<p>05_14_18 Jones Combo V3.184</p>

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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	453:8 Q. Okay. Do you see where it	SCHULTZDEPOSITIONEXHIBITS-1253092.654.3
	453:9 continues, "These experiences have	
	453:10 created a lukewarm opinion of the product	
	453:11 with the sales team and resulted in lost	
	453:12 business opportunities"?	
	453:13 A. Yes.	
453:22 - 454:9	Shultz, Gin 01-30-2014 (00:00:24)	05_14_18 Jones Combo V3.185
	453:22 Q. It continues, "This project	SCHULTZDEPOSITIONEXHIBITS-1253092.654.4
	453:23 should not only reduce physical	
	453:24 complications but should also help	
	454:1 address psychological reservations, both	
	454:2 in the sales teams and with customers	
	454:3 regarding BPV optional filters."	
	454:4 Do you see that?	
	454:5 A. Yes.	
	454:6 Q. Okay. So adding caudal	
	454:7 anchors to Bard's optional filters was --	
	454:8 it was believed that it was going to	
	454:9 reduce physical complications, correct?	
454:12 - 454:14	Shultz, Gin 01-30-2014 (00:00:03)	05_14_18 Jones Combo V3.186
	454:12 THE WITNESS: The POA	
	454:13 statement -- has that statement in	
	454:14 it, yes.	
454:16 - 455:2	Shultz, Gin 01-30-2014 (00:00:25)	05_14_18 Jones Combo V3.187
	454:16 Q. Okay. Do you have any	clear
	454:17 recollection of why -- why caudal anchors	
	454:18 were being added to the filters?	
	454:19 A. The -- to give the filter a	
	454:20 positional stability so you would reduce	
	454:21 tilting and other complications that come	
	454:22 from it.	
	454:23 Q. That result from tilting?	
	454:24 A. That result from tilting.	
	455:1 Q. Such as fracture?	
	455:2 A. And perforation.	
455:10 - 455:11	Shultz, Gin 01-30-2014 (00:00:03)	05_14_18 Jones Combo V3.188
	455:10 Q. Okay. I'm going to hand you	SCHULTZDEPOSITIONEXHIBITS-1253092.656.9
	455:11 what we'll mark as Exhibit Number 21.	
456:1 - 456:6	Shultz, Gin 01-30-2014 (00:00:11)	05_14_18 Jones Combo V3.189
	456:1 Q. Do you agree that this	

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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	456:2 appears to be an e-mail with an 456:3 attachment from Brian Hudson to some 456:4 Bard -- two Bard employees, dated 456:5 June 28, 2011? 456:6 A. Yes.	SCHULTZDEPOSITIONEXHIBITS-1253092.656.2
457:6 - 457:10	Shultz, Gin 01-30-2014 (00:00:11) 457:6 Q. Okay. Under subject, it 457:7 says, "Fracture talking points." And 457:8 attachment, it says, "Filter data 457:9 6/27/11," right? 457:10 A. Yes.	05_14_18 Jones Combo V3.190
457:19 - 457:22	Shultz, Gin 01-30-2014 (00:00:09) 457:19 Q. For the Simon Nitinol 457:20 filter, there were 80,187 devices sold, 457:21 right? 457:22 A. Yes.	05_14_18 Jones Combo V3.191 SCHULTZDEPOSITIONEXHIBITS-1253092.659.5
458:5 - 458:9	Shultz, Gin 01-30-2014 (00:00:07) 458:5 Q. And the Simon Nitinol 458:6 filter, out of the 80,000-plus units 458:7 sold, had eight fracture complaints, 458:8 right? 458:9 A. Yes.	05_14_18 Jones Combo V3.192 SCHULTZDEPOSITIONEXHIBITS-1253092.659.6
459:20 - 460:2	Shultz, Gin 01-30-2014 (00:00:21) 459:20 Q. Okay. Look for me at the G2 459:21 filter. It's got 156 fracture complaints 459:22 and it had a -- it looks like 126,369 459:23 devices sold, right? 459:24 A. Yes. 460:1 Q. And its rate is 460:2 .123 percent, right?	05_14_18 Jones Combo V3.193 clear
460:3 - 460:6	Shultz, Gin 01-30-2014 (00:00:06) 460:3 A. Yes. 460:4 Q. So it's 12.3 out of every 460:5 thousand, right? 460:6 A. Yes.	05_14_18 Jones Combo V3.194
460:20 - 461:6	Shultz, Gin 01-30-2014 (00:00:27) 460:20 The rate for -- according to 460:21 this document, for the G2 for fracture 460:22 complaints was 12 times higher than that 460:23 for the Simon Nitinol filter, correct?	05_14_18 Jones Combo V3.195 SCHULTZDEPOSITIONEXHIBITS-1253092.659.19

05_14_18 Jones Combo V3-Schultz 01-30-14 Jones Trial Designations V3

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	460:24 A. Correct.	
	461:1 Q. Okay. Now, again, as far as	
	461:2 you're aware, failure rate information	
	461:3 regarding the higher reported failure	
	461:4 rates for the Recovery and G2 filter	
	461:5 versus the Simon Nitinol filter was never	
	461:6 shared with consumers, correct?	
461:9 - 461:9	Shultz, Gin 01-30-2014 (00:00:01)	05_14_18 Jones Combo V3.196
	461:9 THE WITNESS: Correct.	
467:23 - 468:15	Shultz, Gin 01-30-2014 (00:00:40)	05_14_18 Jones Combo V3.197
	467:23 Q. Are you aware of the	clear
	467:24 Cantwell study where he compared the	
	468:1 Recovery and G2 filter?	
	468:2 A. I'm sure I reviewed --	
	468:3 Q. In 2009?	
	468:4 A. I'm sure I would have	
	468:5 reviewed it.	
	468:6 Q. And he found a -- a	
	468:7 migration rate of 46.7 percent for the G2	
	468:8 filter?	
	468:9 A. I'm sure I read it.	
	468:10 Q. Okay.	
	468:11 A. And whatever numbers you're	
	468:12 reading off, I'm sure they're there.	
	468:13 Q. Did a 40 percent --	
	468:14 46 percent migration rate exceed Bard's	
	468:15 expected migration rate?	
468:18 - 469:13	Shultz, Gin 01-30-2014 (00:00:44)	05_14_18 Jones Combo V3.198
	468:18 THE WITNESS: The details of	
	468:19 the report, I don't remember. But	
	468:20 from what you've stated of	
	468:21 46 percent, if it was true, it	
	468:22 would exceed.	
	468:23 BY MR. BRENES:	
	468:24 Q. Okay. And do you know, did	
	469:1 Bard send this -- or send out a warning	
	469:2 letter to consumers regarding the	
	469:3 findings of Dr. Cantwell?	
	469:4 A. Bard did not send out a	
	469:5 warning letter.	

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469:6 Q. Okay. And do you know he
 469:7 wrote that, "Caudal migration is thought
 469:8 to be rare and that the incidence
 469:9 observed with caudal migration of the G2
 469:10 filter in this case was beyond what had
 469:11 been previously been reported"?
 469:12 A. I'm sure what you're reading
 469:13 is correct, so...

469:14 - 469:17

Shultz, Gin 01-30-2014 (00:00:09)

05_14_18 Jones Combo V3.199

469:14 Q. Was that concerning
 469:15 to Bard that this study had found failure
 469:16 rates beyond what had previously been
 469:17 reported in the medical literature?

469:22 - 470:1

Shultz, Gin 01-30-2014 (00:00:09)

05_14_18 Jones Combo V3.200

469:22 A. We would evaluate it to
 469:23 determine if the data was valid. We
 469:24 would fill out a complaint. We would
 470:1 investigate it.

Plaintiffs Designations = 00:27:23

Defense Designations = 00:11:00

Total Time = 00:38:23

Documents Shown

SCHULTZDEPOSITIONEXHIBITS-1253092

Exhibit O

Designation Run Report

Smith 08-03-17 Jones Trial depo designations V7

Smith, Christopher 08-03-2017

Plaintiffs Designations 00:14:51

Defense Designations 00:02:04

Plaintiffs and Defense Designations 00:02:10

Total Time 00:19:05



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8:5 - 8:7

Smith, Christopher 18-03-2017 (00:00:00)

02_21_18 Cont'd June 17/1

8:5 Q. Mr. Smith, state your full name for the
8:6 record, please.

8:7 A. Christopher Kent Smith.

8:22 - 8:24

Smith, Christopher 18-03-2017 (00:00:00)

02_21_18 Cont'd June 17/2

8:22 Q. And before December of 2010, where were
8:23 you?

8:24 A. At Bard Peripheral Vascular.

8:25 - 9:8

Smith, Christopher 18-03-2017 (00:00:00)

02_21_18 Cont'd June 17/3

8:25 Q. I'm looking at your CV that I was handed
9:1 today. It looks as though there's a company called
9:2 Covidien?

9:3 A. So I came over from Bard to ev3. Ev3 was
9:4 purchased by Covidien. Covidien was then purchased
9:5 by Medtronic.

9:6 Q. I see. And you were at Bard from when to
9:7 when?

9:8 A. 2006 until 2010.

9:9 - 9:14

Smith, Christopher 18-03-2017 (00:00:00)

02_21_18 Cont'd June 17/4

9:9 Q. And it looks as though you were a sales
9:10 rep -- I -- you started there as a territory manager?

9:11 A. That's correct.

9:12 Q. In 2006. And then you were promoted to
9:13 a -- the southeast district manager?

9:14 A. That's correct.

9:15 - 9:25

Smith, Christopher 18-03-2017 (00:00:00)

02_21_18 Cont'd June 17/5

9:15 Q. And that was in --

9:16 A. 2008.

9:17 Q. Does that mean you reported to a regional
9:18 manager?

9:19 A. That's correct.

9:20 Q. Who was your regional manager?

9:21 A. Dan Orms.

9:22 Q. And when you were a territory manager,
9:23 what were your responsibilities?

9:24 A. I was sales, outside -- direct sales, to
9:25 hospital and physician.

20:15 - 21:16

Smith, Christopher 18-03-2017 (00:00:00)

02_21_18 Cont'd June 17/6

20:15 Q. Do you agree that a medical device company
20:16 should always put patient safety as a priority?

05_21_18 Combo Jones V7-Smith 08-03-17 Jones V7-1 depo designations V7

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20:17 A. Yes, sir.

20:18 Q. Patient safety should come over a medical
20:19 device company's interests and profits?

20:20 A. Yes, sir.

20:21 Q. Do you agree that a medical device company
20:22 should thoroughly test a device before launching it
20:23 into the market?

20:24 A. Yes, sir.

20:25 Q. And test it for safety and efficacy?

21:1 A. Absolutely.

21:2 Q. And do you agree that a medical device
21:3 company should have an understanding and research the
21:4 environment, the anatomical environment where the --
21:5 where the device is going to be placed?

21:6 A. Sure. Yes.

21:7 Q. Failure to do so, you agree, would place
21:8 the patient's interest and safety at jeopardy?

21:9 A. I would imagine, yes.

21:10 Q. Is there -- do you agree that a medical
21:11 device company should keep itself apprised of any
21:12 problems or failures that its devices experience
21:13 after they're launched in the market?21:14 A. Yes. Every company I've worked for does
21:15 that.21:16 Q. And take steps to remedy any problems or
21:17 dangers to patients?

21:18 A. Absolutely.

23:21 - 23:23 Smith, Christopher 08-03-2017 (00:00:10)

05_21_18 Combo Jones V7-8

23:21 Q. Doctors rely on sales reps to provide them
23:22 with information, accurate information about the
23:23 devices that they are promoting?

24:2 - 24:3 Smith, Christopher 08-03-2017 (00:00:01)

05_21_18 Combo Jones V7-7

24:2 THE WITNESS: Yes,
24:3 puzzle.

24:10 - 24:19 Smith, Christopher 08-03-2017 (00:00:24)

05_21_18 Combo Jones V7-6

24:10 Q. And you in turn rely on your
24:11 company to provide you with the information necessary
24:12 to talk to doctors and -- and promote your products
24:13 to doctors, correct?

24:14 A. That's correct.

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24:15 Q. And you expect that a company like Bard
24:16 will provide you in sales with all the information
24:17 necessary about a product, including the good and the
24:18 bad?

24:19 A. That's correct.

25:18 - 25:22

Smith, Christopher 18-03-2017 (00:00:11)

PL_21_18_Contra_2017_V710

25:18 Q. And if a company like Bard fails to
25:19 provide you with complete and accurate information,
25:20 that could place your relationship with your doctor
25:21 customers in jeopardy, true?

25:22 A. True.

25:23 - 26:8

Smith, Christopher 18-03-2017 (00:00:21)

PL_21_18_Contra_2017_V710

25:23 Q. in various sales, do you agree
25:24 that you, too, must put patient safety first and
25:25 foremost?

26:1 A. Absolutely.

26:2 Q. And do you agree that in sales, you must
26:3 act in the -- with the highest ethical standards?

26:4 A. Yes.

26:5 Q. And you expect the company that employs
26:6 you to act the same way, with -- at the highest
26:7 ethical standards?

26:8 A. Correct.

29:18 - 29:24

Smith, Christopher 18-03-2017 (00:00:31)

PL_21_18_Contra_2017_V711

29:18 Q. And you knew that there were patients at
29:19 the time you started that had Recovery filters
29:20 implanted, correct?

29:21 A. That's correct.

29:22 Q. And you also had to understand something
29:23 about the Recovery in order to understand the G2.

29:24 Fair?

30:1 - 30:3

Smith, Christopher 18-03-2017 (00:00:41)

PL_21_18_Contra_2017_V711

30:1 THE WITNESS: Yes.

30:2 BY MR. O'CONNOR:

30:3 Q. As a predicate device?

30:5 - 30:10

Smith, Christopher 18-03-2017 (00:00:51)

PL_21_18_Contra_2017_V711

30:5 THE WITNESS: Fair.

30:6 BY MR. O'CONNOR:

30:7 Q. And -- and did you understand that a

30:8 device had to be as safe and as effective as its

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	30:9 predicate device?	
	30:10 A. All medical devices do.	
38:15 - 38:18	Smith, Christopher 18-03-2017 (00:00:11)	15_21_18 Comp Jones 18-03-2017
	38:15 Q. Mr. Smith, we're looking at Exhibit 4055.	
	38:16 It's an e-mail thread between David Rauch and Janet	
	38:17 Hudnall. Did you know David Rauch?	
	38:18 A. No.	
39:3 - 39:4	Smith, Christopher 18-03-2017 (00:00:10)	15_21_18 Comp Jones 18-03-2017
	39:3 Q. Have you ever seen this exhibit before?	
	39:4 A. No.	
39:5 - 39:11	Smith, Christopher 18-03-2017 (00:00:11)	15_21_18 Comp Jones 18-03-2017
	39:5 Q. How did marketing interact with sales?	
	39:6 A. They provided us with brochures. Told us	
	39:7 about product development and taught us about the	
	39:8 product itself, and the engineering design.	
	39:9 Q. Is that something that Janet Hudnall did	
	39:10 for you?	
	39:11 A. Correct, yes.	
41:23 - 42:2	Smith, Christopher 18-03-2017 (00:00:11)	15_21_18 Comp Jones 18-03-2017
	41:23 Q. At any point in time, did you become aware	
	41:24 that Bard had concerns and was aware of problems with	
	41:25 the Recovery in terms of tilt resistance?	
	42:1 ***	
	42:2 THE WITNESS: No.	
42:4 - 42:6	Smith, Christopher 18-03-2017 (00:00:11)	15_21_18 Comp Jones 18-03-2017
	42:4 Q. And you never saw the type of concern	
	42:5 that's stated in Exhibit 4055?	
	42:6 A. No, sir.	
42:18 - 42:25	Smith, Christopher 18-03-2017 (00:00:11)	15_21_18 Comp Jones 18-03-2017
	42:18 Q. And that you expected that Bard would do	
	42:19 the appropriate testing and -- and follow the	
	42:20 appropriate design criteria to -- to address any	
	42:21 problems it was aware of tilt in its filters?	
	42:22 A. Yes.	
	42:23 Q. And if Bard didn't do that, that would	
	42:24 place patient safety in jeopardy; you agree with	
	42:25 that?	
43:2 - 43:2	Smith, Christopher 18-03-2017 (00:00:11)	15_21_18 Comp Jones 18-03-2017
	43:2 THE WITNESS: Yes.	
53:5 - 53:11	Smith, Christopher 18-03-2017 (00:00:11)	15_21_18 Comp Jones 18-03-2017

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77:15 - 77:16	77:11 adequately test for migration resistance, improved 77:12 centering, or fracture resistance, do you agree that 77:13 that would place patient safety in jeopardy? Smith, Christopher 08-03-2017 (00:00:00)	00_01_18 Conclusions (1731)
80:1 - 80:9	77:15 THE WITNESS: You know, I -- again -- 77:16 again, it's assumption. Yes. Smith, Christopher 08-03-2017 (00:00:01)	00_01_18 Conclusions (1731)
81:6 - 81:9	80:1 Q. So one thing that you were promoting to 80:2 the doctors is that the G2, when it was implanted, it 80:3 would become securely fixed to the vena cava wall in 80:4 the position where it was intended to be. Fair? 80:5 A. That's correct. 80:6 Q. And as a permanent device, that the intent 80:7 was that it would remain in that position for the 80:8 duration of a patient's life? 80:9 A. That's correct. Smith, Christopher 08-03-2017 (00:00:02)	00_01_18 Conclusions (1731)
81:24 - 82:1	81:6 Q. This is 4062. And this is an e-mail from 81:7 David Ciavarella, who was a medical director at that 81:8 time. Do you see that? 81:9 A. I do. Smith, Christopher 08-03-2017 (00:00:03)	00_01_18 Conclusions (1731)
83:21 - 84:6	81:24 Q. The subject is "G2 caudal migrations," and 81:25 again, this is dated December 27, 2005. 82:1 A. Okay. Smith, Christopher 08-03-2017 (00:00:04)	00_01_18 Conclusions (1731)
84:17 - 85:9	83:21 THE WITNESS: When you say "concern," yes. 83:22 Again, we were mentioned complications, but yes, 83:23 that would be correct. 83:24 BY MR. O'CONNOR: 83:25 Q. You weren't apprised of -- of the subject 84:1 matter in this e-mail, were you? 84:2 A. No. 84:3 Q. And were you ever told that the medical 84:4 director had asked the question about G2 complaints? 84:5 A. No. Again, I didn't even know who the 84:6 medical director was. Smith, Christopher 08-03-2017 (00:00:05)	00_01_18 Conclusions (1731)
	84:17 Q. Now, you told me that you were involved in 84:18 promoting the Simon Nitinol filter, correct?	

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84:19 A. Yes, I sold -- it was part of our bag,
84:20 yes.

84:21 Q. And when you arrived at Bard, were you
84:22 told -- or at any time told that the SNF had
84:23 virtually no complaints?

84:24 A. Yes. It was a very safe filter.

84:25 Q. And were you told that the G2 filter did
85:1 have complaints and concerns in Bard?

85:2 ****

85:3 THE WITNESS: Yes, there were complaints.

85:4 BY MR. O'CONNOR:

85:5 Q. Okay. And -- and were you told that Bard
85:6 even had questioned why were they -- about the safety
85:7 and efficacy of the G2?

85:8 ****

85:9 THE WITNESS: No.

94:2 - 94:9

Smith, Christopher 18-03-2017 (00:00:00)

03_21_18 Complaints VY 23

94:2 Q. Certainly doctors were communicating with
94:3 you about filters and filter complications, right?

94:4 A. Yes, all doctors were aware that there
94:5 were complications with all IVC filters.

94:6 Q. Well, that's -- my question is a little
94:7 different. You don't know what each individual
94:8 doctor was aware of. Fair?

94:9 A. That's correct.

94:10 - 95:10

Smith, Christopher 18-03-2017 (00:01:00)

03_21_18 Complaints VY 24

94:10 Q. But in terms of where you were, your
94:11 position at Bard, it was not unusual for you to
94:12 receive a call or a communication from a doctor if he
94:13 or she had a question or a concern about a filter,
94:14 fair?

94:15 A. I don't know if I'd say "unusual," but
94:16 I -- you would receive calls or have conversations
94:17 about that, yes.

94:18 Q. And you wanted to make sure that you had
94:19 the best and most accurate information to address any
94:20 issues raised by doctors to you, fair?

94:21 A. Sure.

94:22 Q. That goes to the whole issue that we
94:23 talked about earlier: Trust. Right?

05-21-18 Court Reporters - Smith 08-03-2017

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94:24 A. Uh-huh.

94:25 Q. Yes?

95:1 A. Yes.

95:2 Q. So if Bard had information about tracking

95:3 and trending complications in specific filters, would

95:4 you expect Bard to communicate that to you so you

95:5 could advise your doctors?

95:6 A. Unless there was a major concern with it,

95:7 no.

95:8 Q. A major concern would be if the filter was

95:9 causing complications in patients?

95:10 A. Correct.

120:1 - 120:21

Smith, Christopher 08-03-2017 (00:00:57)

05-21-18 Court Reporters - Smith

120:1 Q. 4065. And this is another e-mail dated

120:2 May 19, 2006, from Natalie Wong. Do you see that?

120:3 A. Yes.

120:4 Q. And it talks about a G2 caudal summary and

120:5 RNF or Recovery nitinol filter fracture report. Do

120:6 you see that?

120:7 A. Yes.

120:8 Q. And again, this was before you were --

120:9 A. I might have been on -- I believe it was

120:10 March, April time frame that I came on board.

120:11 Q. No, no, no, you weren't here yet, because

120:12 it's dated May 19, 2006.

120:13 A. Right. And I'd have to go back and look.

120:14 I'm not speaking -- but I believe I came in April of

120:15 2006.

120:16 Q. Oh, that's right, I -- you're correct.

120:17 Certainly this is not a document that was

120:18 presented to you?

120:19 A. That's correct.

120:20 Q. And you were unaware of any attempts to --

120:21 to analyze a fracture in any of the filter?

120:23 - 121:15

Smith, Christopher 08-03-2017 (00:00:58)

05-21-18 Court Reporters - Smith

120:23 THE WITNESS: To my knowledge, no.

120:24

120:25 BY MR. O'CONNOR:

121:1 Q. Assuming you were there, certainly nobody

121:2 told you about a fracture analysis that was done with

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121:3 respect to the Recovery?

121:4 A. No.

121:5 Q. But you knew the product -- the Recovery
121:6 was the predicate to the G2?

121:7 A. That's correct.

121:8 Q. And you knew the G2 was the predicate to
121:9 the Eclipse?

121:10 A. That's correct.

121:11 Q. And what you did expect is that if Bard
121:12 became aware of complications, that it would take
121:13 steps to -- to do whatever was necessary to protect
121:14 patients from their injuries associated with those
121:15 complications, correct?

121:17 - 121:21 Smith, Christopher 18-03-2017 (00:00:00)

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121:17 THE WITNESS: Yes, I felt they did.

121:18 BY MR. O'CONNOR:

121:19 Q. Well, that's certainly something you
121:20 expected, right?

121:21 A. Correct.

124:3 - 124:10 Smith, Christopher 18-03-2017 (00:00:00)

18-03-2017 08-03-2017

124:3 Q. And if you look, it says "129 pieces
124:4 remain implanted in 76 patients."

124:5 Do you see that?

124:6 A. Yes.

124:7 Q. And -- and it's talking about, in this
124:8 case, pieces of filter that have detached from the
124:9 body of the filter?

124:10 A. Correct.

124:13 - 124:19 Smith, Christopher 18-03-2017 (00:00:00)

18-03-2017 08-03-2017

124:13 Q. You've never seen this type of an
124:14 analysis?

124:15 A. No. I have not.

124:16 Q. But certainly, you would expect that Bard
124:17 would take steps to prevent filter fracture
124:18 detachment, to avoid having fragments retained in
124:19 patients, correct?

124:21 - 124:21 Smith, Christopher 18-03-2017 (00:00:00)

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124:21 THE WITNESS: Yes.

125:24 - 125:24 Smith, Christopher 18-03-2017 (00:00:00)

18-03-2017 08-03-2017

125:24 Q. And one thing that you were

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125:25 promoting when you promoted the Eclipse was a filter

126:1 that was improved by way of stability, centering,

126:2 including migration resistant, correct?

126:3 ***

126:4 THE WITNESS: That was the G2, yes.

126:5 BY MR. O'CONNOR:

126:6 Q. And -- and one that was resistant to

126:7 fracture, as we saw?

126:9 - 126:18 Smith, Christopher 08-03-2017 (00:00:11)

126:9 THE WITNESS: The Eclipse filter was

126:10 determined to be less resistant due to the

126:11 electropolishing, yes.

126:12 BY MR. O'CONNOR:

126:13 Q. More resistant?

126:14 A. Yes, more resistant to fracture, correct,

126:15 yes.

126:16 Q. I mean, that's how you promoted it?

126:17 ****

126:18 THE WITNESS: That is correct.

128:9 - 128:15 Smith, Christopher 08-03-2017 (00:00:11)

128:9 Q. The way that you and sales were promoting

128:10 the G2 and the Eclipse was that among other things,

128:11 it was fracture -- resistant to fracture?

128:12 A. Uh-huh. Yes.

128:13 Q. And you understood that physicians were

128:14 relying on those representations as accurate,

128:15 correct?

128:17 - 129:4 Smith, Christopher 08-03-2017 (00:00:11)

128:17 THE WITNESS: One piece of it, yes, would

128:18 be from the sales rep.

128:19 BY MR. O'CONNOR:

128:20 Q. I understand. One piece of it is from the

128:21 sales rep, and the sales reps relied on Bard to give

128:22 them information, right?

128:23 A. That's how we got our information, yes.

128:24 Q. Okay. And you would expect that Bard

128:25 would have taken steps to improve both the G2 and the

129:1 Eclipse in terms of fracture resistance, correct?

129:2 ***

129:3 THE WITNESS: That was my understanding,

05-20-18 Combo J. Jones 17-Smith 08-03-17 J. Jones al nepo designation v/

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129:4 yes.
 136:1 - 136:18 Smith, Christopher 08-03-2017 (00:00:1
 136:1 Q. But you were never provided any
 136:2 information where Bard stated that they were
 136:3 concerned about the caudal migration, tilt,
 136:4 perforation, and fractures being most -- most
 136:5 commonly occurring in the G2?
 136:6 A. I was not --
 136:7
 136:8 THE WITNESS: -- given any specific data,
 136:9 no.
 136:10 BY MR. O'CONNOR:
 136:11 Q. But you understood when you were promoting
 136:12 the G2 that it was designed to be resistant to these
 136:13 complications, right?
 136:14 A. That's correct.
 136:15 Q. And certainly, you would expect Bard to
 136:16 take steps to -- to eliminate these type of failure
 136:17 modes, correct?
 136:18 A. Correct.
 136:19 - 136:22 Smith, Christopher 08-03-2017 (00:00:1
 136:19 Q. And that if there was another iteration of
 136:20 the filter, that that filter would be designed and
 136:21 tested to confirm that these failure modes were
 136:22 reduced or eliminated?
 136:24 - 137:1 Smith, Christopher 08-03-2017 (00:00:1
 136:24 THE WITNESS: I think the goal would be
 136:25 for reduce; ultimately, elimination. But I
 137:1 don't think that's possible.
 137:14 - 137:21 Smith, Christopher 08-03-2017 (00:00:2
 137:14 Q. Go to page 16. It says "Relationships."
 137:15 It says, "It is believed that caudal migration leads
 137:16 to tilts, perforation, and fractures."
 137:17 Did I read that correctly?
 137:18 A. Yes.
 137:19 Q. Is that something you understood?
 137:20 A. That's what I was taught, yes, it could
 137:21 be.
 144:1 - 144:15 Smith, Christopher 08-03-2017 (00:00:2
 144:1 Q. And so if Bard was becoming aware of any

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144:2 risks, increased risks or failure modes, increased
 144:3 failure modes with any filter model, and it wanted to
 144:4 communicate that information to doctors, it could
 144:5 communicate through the sales force, tell you to
 144:6 advise your doctors that this filter is experiencing
 144:7 problems?

144:8 A. I don't think just -- it's not the filters
 144:9 to any device is out there.

144:10 Q. And -- and understand, I'm just here to
 144:11 talk about filters, but --

144:12 A. Sure.

144:13 Q. -- I think we're on the same page. You
 144:14 agree with that statement?

144:15 A. Yes.

159:6 - 159:11 Smith, Christopher 08-23-2017 (00:00:00)

159:6 Q. And as far as you know, Bard never in any
 159:7 document advised doctors or patients of a time limit
 159:8 when a filter should be removed. Fair?

159:9 ****

159:10 THE WITNESS: My understanding was it was
 159:11 up to the physician.

159:13 - 159:20 Smith, Christopher 08-23-2017 (00:00:00)

159:13 Q. But also it's your understanding
 159:14 that Bard certainly never put in any document, an IFU
 159:15 or anything, a specific time and limit when it should
 159:16 be removed?

159:17 A. I can't answer that question because I
 159:18 don't know the answer.

159:19 Q. You never heard of one or saw one?

159:20 A. Me personally, no.

160:21 - 160:25 Smith, Christopher 08-23-2017 (00:00:00)

160:21 Q. Certainly, if Bard became aware of a
 160:22 relationship between the length of indwell time and
 160:23 increased risk of complications, that would be
 160:24 important information to share with physicians,
 160:25 correct?

161:2 - 161:5 Smith, Christopher 08-23-2017 (00:00:00)

161:2 THE WITNESS: That, I don't believe so.
 161:3 You -- it would have to be tested. I think it's
 161:4 something -- it's a theory, so I think that

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161:24 - 162:3	161:5 there'd be more testing needed. Smith, Christopher 08-03-2017 (00:00:00)	000000000000000000
162:6 - 162:20	161:24 Q. If 161:25 Bard was aware of a relationship between indwell time 162:1 and complications, number one, you believe that's 162:2 something they should be -- Bard should be 162:3 communicating to doctors. Fair? Smith, Christopher 08-03-2017 (00:00:00) 162:6 THE WITNESS: I think it's a more 162:7 complicated question than you're asking. 162:8 BY MR. O'CONNOR: 162:9 Q. Well, I'm just asking if -- 162:10 A. And I can't answer it with just a yes or 162:11 no. 162:12 Q. If Bard was aware of that -- 162:13 A. There's too many variables. Under what 162:14 circumstances did they become aware? Was it a 162:15 single-center study? Was it a multicenter study? 162:16 Was it a comparative? 162:17 I need -- I would need to know more 162:18 information to answer your question. If it was a 162:19 multicenter-faceted, prospective study, yes. If it 162:20 was a single-arm study that was done on a pig, no.	000000000000000000
164:8 - 164:13	Smith, Christopher 08-03-2017 (00:00:00) 164:8 Q. Could you go ahead and answer that first, 164:9 so we can move on? 164:10 A. I believe it's a more complicated question 164:11 than a yes or no. Yes, I think if they can pound 164:12 into more data, the correlation between the two, I 164:13 think that needs to be studied further.	000000000000000000
165:2 - 165:8	Smith, Christopher 08-03-2017 (00:00:00) 165:2 Q. Patient safety always has to come first, 165:3 right? 165:4 A. Agreed. 165:5 Q. And Bard has to communicate with doctors 165:6 anything that's necessary to promote patient safety, 165:7 right? 165:8 A. I believe they do, yes.	000000000000000000
178:23 - 178:23	Smith, Christopher 08-03-2017 (00:00:00) 178:23 COURT REPORTER: 4074.	000000000000000000

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181:9 - 181:18 Smith, Christopher 18-03-2017 (00:00:00)

181:9 Q. In fairness, you understood that
 181:10 that had been an issue for Bard -- with Bard filters
 181:11 while you were there?
 181:12 ****

181:13 THE WITNESS: I believe it was not -- I
 181:14 won't say issue. I think it was a complication.
 181:15 BY MR. O'CONNOR:

181:16 Q. A complication that Bard was aware of?
 181:17 A. I think everyone, every filter on the
 181:18 market was aware caudal migration could be an issue.

181:19 - 181:23 Smith, Christopher 18-03-2017 (00:00:00)

181:19 Q. But in terms of what we've looked at
 181:20 today, you can see that Bard was certainly looking at
 181:21 this as early as 2006, right?
 181:22 *****

181:23 THE WITNESS: They were studying it, yes.

182:1 - 182:3 Smith, Christopher 18-03-2017 (00:00:00)

182:1 Q. And nothing had changed in the
 182:2 design all the way to the Eclipse that addressed
 182:3 caudal migration, correct?

182:5 - 182:6 Smith, Christopher 18-03-2017 (00:00:00)

182:5 THE WITNESS: I can't answer that, what
 182:6 was done.

186:13 - 186:16 Smith, Christopher 18-03-2017 (00:00:00)

186:13 Q. And if an enhancement to resist fracture
 186:14 was a feature, that's certainly something that you
 186:15 were providing to a doctor based upon their
 186:16 expectations, right?

186:18 - 186:21 Smith, Christopher 18-03-2017 (00:00:00)

186:18 THE WITNESS: Yes.

186:19 BY MR. O'CONNOR:

186:20 Q. And doctors, you can understand, and
 186:21 patients, wanted filters that would not fracture?

186:23 - 186:23 Smith, Christopher 18-03-2017 (00:00:00)

186:23 THE WITNESS: Yes.

187:14 - 187:18 Smith, Christopher 18-03-2017 (00:00:00)

187:14 Q. Did you know -- go to page 4 of
 187:15 Exhibit 4074. Now, I think we can both agree that
 187:16 the -- Bard was working on the Meridian while the

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187:17 Eclipse was being promoted out in the market, right?

187:18 A. Yes.

189:7 - 189:8

Smith, Christopher 08-03-2017 (00:00:00)

189:7 Q. Did you know a doctor named Anthony Avino?

189:8 A. Yes, I did.

189:22 - 190:15

Smith, Christopher 08-03-2017 (00:00:00)

189:22 Q. What group was he with?

189:23 A. Savannah Vascular.

189:24 Q. And -- and Melanie, do you know where

189:25 she's at these days?

190:1 A. She's retired.

190:2 Q. But she was somebody who reported to you?

190:3 A. She did.

190:4 Q. And she was on your sales force?

190:5 A. Yes.

190:6 Q. And you, like all your sales force, wanted

190:7 them to promote the filters consistent with the

190:8 information received from Bard, correct?

190:9 A. Yes.

190:10 Q. And when it came time to promote the

190:11 Eclipse, it was your expectation that Melanie was

190:12 going to promote the Eclipse as a filter that was

190:13 resistant to tilt, migration, and fracture?

190:14 ****

190:15 THE WITNESS: My understanding, yes.

191:21 - 191:25

Smith, Christopher 08-03-2017 (00:00:00)

191:21 Q. And that a filter being implanted with the

191:22 Eclipse, with everything that was represented, you

191:23 agree that a fractured strut embolizing to the

191:24 pulmonary artery would be contrary to that patient's

191:25 expectations?

192:2 - 192:9

Smith, Christopher 08-03-2017 (00:00:00)

192:2 THE WITNESS: I've never had a vena cava

192:3 filter implanted, and I've never talked to a

192:4 physician about their exact expectations about a

192:5 pulmonary -- or a fracture going into the

192:6 pulmonary artery.

192:7 BY MR. O'CONNOR:

192:8 Q. Would that make sense to you, though?

192:9 A. It would make sense, yes.

05_21_18 Combo Jones V7-Smith 08-03-17 Jones V7 al depo designations V7

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Plaintiffs Designations = 00:14:51

Defense Designations = 00:02:04

Plaintiffs and Defense Designations = 00:02:10

Total Time = 00:19:05

Exhibit P

Designation Run Report

Sussman_COMBO_0524_R02

Sussman, Melanie 04-07-2017

PL 00:04:26

DEF 00:29:00

Total Time 00:33:26



Sussman_COMBO_0524_R02

Page/Line	Source	ID
7:11 - 7:12	Sussman, Melanie 04-07-2017 (00:00:01) 7:11 Q. Good morning, Ms. Sussman. 7:12 A. Good morning.	Sussman_COMBO_0524_R02.1
32:17 - 33:1	Sussman, Melanie 04-07-2017 (00:00:17) 32:17 Q. Where did you -- where did you go to 32:18 undergraduate -- where did you go to college? 32:19 A. University of Florida. 32:20 Q. And what year did you graduate? 32:21 A. '91. 32:22 Q. And it looks like you had a communications -- 32:23 you were a communications major, so you have a degree 32:24 in communication and a bachelor of science in 32:25 journalism; is that correct? 33:1 A. That is correct.	Sussman_COMBO_0524_R02.3
38:6 - 38:10	Sussman, Melanie 04-07-2017 (00:00:23) 38:6 Q. And what were you selling? 38:7 A. At the time we were Bard Radiology and I sold 38:8 angioplasty balloons, stents, IVC filters, some 38:9 biopsy devices, and I believe those were the product 38:10 categories.	Sussman_COMBO_0524_R02.6
38:20 - 39:1	Sussman, Melanie 04-07-2017 (00:00:17) 38:20 Q. Okay. Did you consistently sell IVC filters 38:21 from March of '98 until you left Bard in March of 38:22 2013? 38:23 A. Yes. 38:24 Q. What IVC filter -- filter or filters were you 38:25 selling in 1998? 39:1 A. In 1998 the Simon Nitinol filter.	Sussman_COMBO_0524_R02.7
39:22 - 40:4	Sussman, Melanie 04-07-2017 (00:00:15) 39:22 Q. At some point did you start selling other IVC 39:23 filters for Bard? 39:24 A. Yes. 39:25 Q. Do you recall when that was and what the 40:1 filter -- the next filter you sold was? 40:2 A. The next filter was the Recovery filter, and 40:3 I could not tell you the year unless I went back and 40:4 looked.	Sussman_COMBO_0524_R02.9
42:23 - 43:8	Sussman, Melanie 04-07-2017 (00:00:37) 42:23 Was it your understanding that when the 42:24 Eclipse filter came out, that you were to continue to	Sussman_COMBO_0524_R02.11

Sussman_COMBO_0524_R02

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42:25 sell the G2 and G2X?

43:1 A. I know there were some physicians that --

43:2 there are always physicians that like to use newer

43:3 products when they come out, and then there are

43:4 always physicians that say they would like to wait

43:5 until the data is out on new devices. So we

43:6 continued to sell the Simon Nitinol filter, the G2,

43:7 G2X, so there are some physicians that prefer one or

43:8 the other for various reasons.

44:17 - 45:1

Sussman, Melanie 04-07-2017 (00:00:35)

Sussman_COMBO_0524_R02.12

44:17 Q. Do you know if you were selling the Eclipse

44:18 filter in March of 2013?

44:19 A. I believe -- I'm not sure. I believe so.

44:20 Q. Do you -- are you familiar with what

44:21 generation of filter came after the Eclipse filter?

44:22 A. The Meridian filter.

44:23 Q. And are you familiar -- what was different

44:24 about the Meridian filter from the Eclipse filter if

44:25 you recall?

45:1 A. It had anchors on the feet.

55:12 - 55:23

Sussman, Melanie 04-07-2017 (00:00:35)

Sussman_COMBO_0524_R02.13

55:12 You talked about maintaining your territory,

55:13 attending cases, working with physicians and

55:14 clinicians.

55:15 In terms of maintaining your territory, what

55:16 did you mean -- what do you mean by that?

55:17 A. We were expected to enlighten physicians on

55:18 any new devices we had, delivery systems, attend

55:19 cases, that kind of thing.

55:20 Q. Did you have a quota for the number of

55:21 meetings you were supposed to have with physicians

55:22 during your time as a sales representative at Bard?

55:23 A. No.

67:12 - 67:24

Sussman, Melanie 04-07-2017 (00:00:41)

Sussman_COMBO_0524_R02.14

67:12 Q. In 2010, to the extent you can recall, who

67:13 were your larger accounts?

67:14 A. In 2010, I believe Augusta Vascular, Savannah

67:15 Vascular. I could -- oh, I can't look at this. I'm

67:16 going to have to go back and look at a different one

67:17 at this point.

Sussman_COMBO_0524_R02

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67:18 Q. Yeah. What about -- where does Memorial
67:19 Hospital fit in there?

67:20 A. Memorial Hospital -- sorry. Savannah

67:21 Vascular is part of Memorial Hospital.

67:22 Q. Did you -- were the filters sold to Savannah

67:23 Vascular or Memorial Hospital, or both?

67:24 A. Both.

68:5 - 68:19

Sussman, Melanie 04-07-2017 (00:00:40)

Sussman_COMBO_0524_R02.15

68:5 Q. I believe, based on our discussion earlier,
68:6 that you resigned from Bard in March of 2013?

68:7 A. I did.

68:8 Q. You were there for a long time. What made
68:9 you decide to leave?

68:10 A. My kids.

68:11 Q. How old were your kids at the time?

68:12 A. At that time? In 2013 they would have been
68:13 eight and five.

68:14 Q. A busy time?

68:15 A. It is. It's always busy.

68:16 Q. Now, you're married?

68:17 A. I am.

68:18 Q. Okay. Who are you married to?

68:19 A. Tony Sussman.

68:20 - 69:2

Sussman, Melanie 04-07-2017 (00:00:12)

Sussman_COMBO_0524_R02.16

68:20 Q. Okay. And is he a physician at Savannah

68:21 Vascular?

68:22 A. He is.

68:23 Q. Okay. He's one of the founders of Savannah

68:24 Vascular, right?

68:25 A. Yes.

69:1 Q. Okay. And when did you get married?

69:2 A. 2004.

74:23 - 75:1

Sussman, Melanie 04-07-2017 (00:00:16)

Sussman_COMBO_0524_R02.17

74:23 When you were selling IVC filters to your

74:24 customers -- or to Bard's customers, those customers

74:25 were doctors, correct, and hospitals?

75:1 A. Doctors and hospitals, coordinators, but yes.

75:8 - 75:23

Sussman, Melanie 04-07-2017 (00:00:37)

Sussman_COMBO_0524_R02.18

75:8 Q. You would agree with me that in selling

75:9 medical devices to a physician, safety is a primary

Sussman_COMBO_0524_R02

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75:10 concern -- safety of the patient is a primary concern

75:11 of yours, correct?

75:12 A. Safety is always a concern.

75:13 Q. And that's a primary concern of the

75:14 physicians that you're selling the filters to,

75:15 correct?

75:16 A. It's always a focus, of course, yes.

75:17 Q. And patient safety is really an important

75:18 focus, correct?

75:19 A. That is correct.

75:20 Q. And in your experience as a sales

75:21 representative, is it safe to say that your doctors

75:22 that you interacted with wanted to implant the safest

75:23 device possible in their patients?

75:25 - 76:9

Sussman, Melanie 04-07-2017 (00:00:27)

Sussman_COMBO_0524_R02.19

75:25 A. I don't know that you could really say what

76:1 is the safest device. There are lots of devices out

76:2 there and physicians use different devices for

76:3 different reasons. I think safety is always a

76:4 concern for the company and for physicians and for

76:5 the patient.

76:6 Q. Sure. And if you're talking IVC filters, for

76:7 example, the physicians are going to want to use the

76:8 safest IVC filter available on the market in their

76:9 patients, correct?

76:11 - 76:13

Sussman, Melanie 04-07-2017 (00:00:10)

Sussman_COMBO_0524_R02.20

76:11 A. They certainly want to use safe devices. I

76:12 don't think there is any way that you can say what is

76:13 the safest device. There are so many different --

78:7 - 78:12

Sussman, Melanie 04-07-2017 (00:00:22)

Sussman_COMBO_0524_R02.22

78:7 Q. So you rely then on Bard to provide you with

78:8 accurate information that you can then convey to your

78:9 physicians, correct?

78:10 A. Yes. But, of course, they are going to

78:11 take -- they have all kinds of resources other than

78:12 just information that I give them or Bard gives them.

78:14 - 78:19

Sussman, Melanie 04-07-2017 (00:00:13)

Sussman_COMBO_0524_R02.23

78:14 sometimes in your role as a sales representative,

78:15 there would be an article in a medical journal that

78:16 they may perhaps have read and you would get a

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78:17 communication from Bard informing you with talking
78:18 points to discuss those articles with your physicians,
78:19 correct?

78:21 - 78:23

Sussman, Melanie 04-07-2017 (00:00:10)

Sussman_COMBO_0524_R02.24

78:21 A. They made us aware of them. I wouldn't say
78:22 that doctors really take our input on clinical
78:23 studies.

81:9 - 82:1

Sussman, Melanie 04-07-2017 (00:01:09)

Sussman_COMBO_0524_R02.25

81:9 A. Keep it in my head for listening to other
81:10 doctors, and understand -- say that I've heard that
81:11 before or from other physicians.
81:12 Q. Were you at any time asked to provide Bard
81:13 with feedback from physicians?
81:14 A. Certainly.
81:15 Q. Was that part of your role as a sales
81:16 representative, to provide Bard with feedback from
81:17 physicians?
81:18 A. Yes, of course. I got a lot of feedback on
81:19 suggestions for delivery and deployment, things that
81:20 would make something easier for the physician, and so
81:21 we would always get that information back to Bard.
81:22 Q. In your role as a sales representative, were
81:23 you expected to discuss any concerns that physician --
81:24 your physicians had with regard to IVC filters?
81:25 A. If they had a concern, then I certainly
82:1 relayed it, yes.

87:12 - 87:15

Sussman, Melanie 04-07-2017 (00:00:14)

Sussman_COMBO_0524_R02.26

87:12 How would you describe your role as a
87:13 salesperson for Bard?

87:14 A. To be knowledgeable about our products, to
87:15 meet with physicians, to attend cases.

87:16 - 87:23

Sussman, Melanie 04-07-2017 (00:00:29)

Sussman_COMBO_0524_R02.27

87:16 Q. When you say be knowledgeable about our
87:17 products, let's take IVC filters, what do you mean by
87:18 that?

87:19 A. Make sure we know how to deliver the device,
87:20 how to relay those steps to the physicians, and know
87:21 what French size it is, know whether you can go from
87:22 different deployment -- different areas in the body
87:23 for insertion, those kinds of things.

Sussman_COMBO_0524_R02

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89:23 - 90:9

Sussman, Melanie 04-07-2017 (00:00:40)

Sussman_COMBO_0524_R02.28

89:23 Q. Okay. You said you would meet with the
89:24 physicians as part of your -- as a salesperson for
89:25 Bard. What did you mean by meet with physicians?

90:1 A. Face-to-face meetings, obviously, going to
90:2 cases, and work with them.

90:3 Q. What -- the face-to-face meetings, what were
90:4 the purpose of the face-to-face meetings?

90:5 A. To see if they had any questions, to talk to
90:6 them about their experiences, that kind of thing.

90:7 Q. Would they -- would you discuss any concerns
90:8 they had with them at these face-to-face meetings?

90:9 A. If they had a concern, then certainly.

97:7 - 98:22

Sussman, Melanie 04-07-2017 (00:01:59)

Sussman_COMBO_0524_R02.29

97:7 Were you ever provided a medical journal article from
97:8 folks at Bard saying pass this along to your
97:9 physicians?

97:10 A. So they would give us the materials because
97:11 they knew that they were being read and the
97:12 physicians were going to read them, so that we needed
97:13 to become familiar with them, and -- just so we could
97:14 listen and hear what they had to say and be aware of
97:15 that information. But as far as passing them along,
97:16 I don't think they would even -- I don't think the
97:17 physicians would even think that would carry much
97:18 weight if I were to pass it on. There really are
97:19 no -- I mean, any --

97:20 Q. In terms of --

97:21 A. And when you say articles --

97:22 Q. Medical journal articles.

97:23 A. Okay.

97:24 Q. You're familiar with medical journal
97:25 articles?

98:1 A. Yes, certainly.

98:2 Q. Okay. You had -- we -- in what we had just
98:3 discussed you said that there were times that Bard
98:4 would educate you on medical journal articles or
98:5 provide you with information from medical journal
98:6 articles so you could essentially become familiar with
98:7 them, and then I think you had said "so we could

Sussman_COMBO_0524_R02

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98:8 listen and hear what they had to say and be aware of
98:9 that."

98:10 Meaning that you'd be aware of this for

98:11 purposes of your communications with your physicians,

98:12 correct?

98:13 A. Correct.

98:14 Q. Okay. Well, did Bard have any rules

98:15 regarding your communications related to medical

98:16 journal articles with physicians, with your

98:17 physicians?

98:18 A. That's not really my -- my area of expertise.

98:19 I mean, I'm not there to educate the physicians on

98:20 how to handle their patients and how to -- how to

98:21 ascertain information or how to interpret those, and

98:22 that information.

103:5 - 103:20

Sussman, Melanie 04-07-2017 (00:00:38)

Sussman_COMBO_0524_R02.38

103:5 Q. Yeah. What's your understanding of the MAUDE

103:6 database? I mean, you have some pretty strong

103:7 opinions about it, so I'm trying to understand the

103:8 bases of those opinions and what they are founded on.

103:9 A. The opinions are it was -- it was very

103:10 difficult because a lot of our competitors were out

103:11 there saying you have a certain number of

103:12 complications that really wasn't -- it wasn't

103:13 factual. And so it was -- there was a lot of hype

103:14 from our competitors and we had to go out there and

103:15 have discussions and then it -- in the end, it's just

103:16 not something that you can rely on.

103:17 Q. Is it your understanding that Bard has an

103:18 obligation to report complications related to its

103:19 filters to the FDA?

103:20 A. That's my understanding.

105:14 - 105:24

Sussman, Melanie 04-07-2017 (00:00:24)

Sussman_COMBO_0524_R02.31

105:14 Q. As a sales representative for Bard, if you

105:15 learned of a complication with any filter, you were

105:16 under an obligation to call Quality Assurance and

105:17 report that, correct?

105:18 A. Absolutely.

105:19 Q. Do you have an understanding of whether or

105:20 not that complaint -- strike that.

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105:21 Do you have an understanding as to whether or
 105:22 not complaints that went to Quality Assurance
 105:23 regarding complications involving IVC filters ended up
 105:24 in the MAUDE database?

106:1 - 106:6

Sussman, Melanie 04-07-2017 (00:00:23)

Sussman_COMBO_0524_R02.32

106:1 A. I believe -- I don't know.

106:2 Q. So your understanding of the MAUDE database
 106:3 is that physicians can report, inventory managers can
 106:4 report, but you don't know whether or not there is an
 106:5 obligation on the part of Bard to also report data
 106:6 that ends up in the MAUDE database?

106:8 - 106:25

Sussman, Melanie 04-07-2017 (00:00:43)

Sussman_COMBO_0524_R02.33

106:8 A. I don't know.

106:9 Q. Okay. So as you sit here today, can you
 106:10 really comment on the reliability of the MAUDE
 106:11 database when you're not entirely sure what's in the
 106:12 MAUDE database?

106:13 A. I can say it's completely unreliable.

106:14 Q. And the basis of that is?

106:15 A. That anybody can call up and make a
 106:16 complaint.

106:17 Q. And how do you know that anybody can call up
 106:18 and make a complaint?

106:19 A. I've seen it happen.

106:20 Q. Do you recall when?

106:21 A. I've -- I have heard of inventory managers
 106:22 and when physicians were showing me -- showing me
 106:23 things on the MAUDE database, it -- it just seems
 106:24 completely unreliable and I believe the physicians
 106:25 feel the same way.

107:10 - 107:24

Sussman, Melanie 04-07-2017 (00:00:41)

Sussman_COMBO_0524_R02.34

107:10 Q. Did you ever discuss the MAUDE database with
 107:11 any physicians as it pertained to IVC filters?

107:12 A. They certainly brought it up quite a bit,
 107:13 yes.

107:14 Q. And what did -- what was the general tenor of
 107:15 those discussions?

107:16 A. Your competitor is saying you have a lot of
 107:17 complaints and we, you know, have -- what do you have
 107:18 to say about that.

Sussman_COMBO_0524_R02

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	107:19 Q. And what did -- what did you have to say 107:20 about that in those circumstances? 107:21 A. I said I believe there are many filters in 107:22 that database and the physicians that I know, it's 107:23 not a reliable source of information, and that was 107:24 about the end of the conversation.	
108:13 - 108:24	Sussman, Melanie 04-07-2017 (00:00:34) 108:13 Q. You had mentioned that competitors were 108:14 citing the MAUDE database for complication relate -- 108:15 complication rates related to Bard filters. 108:16 A. Right. 108:17 Q. In your discussions with physicians, it was 108:18 your opinion that the MAUDE database was unreliable 108:19 and you conveyed this opinion, correct? 108:20 A. Yes. 108:21 Q. If a physician wanted to know where to look 108:22 to see what type of complication rates Bard had in 108:23 relation to its competitors, where would you direct a 108:24 physician to look?	Sussman_COMBO_0524_R02.35
109:1 - 109:3	Sussman, Melanie 04-07-2017 (00:00:06) 109:1 A. And there really is not one. There are no 109:2 head-to-head studies and you can't really make 109:3 comparisons.	Sussman_COMBO_0524_R02.36
111:17 - 113:1	Sussman, Melanie 04-07-2017 (00:01:22) 111:17 Q. Okay. Do you know that Dr. Avino is the one 111:18 who implanted her -- 111:19 A. Yes. 111:20 Q. -- IVC filter? Okay. And Dr. Avino is a 111:21 partner of your husband's; is that correct? 111:22 A. That is correct. 111:23 Q. And Dr. Avino is one of the physicians 111:24 that was one of the -- your physicians during your 111:25 time at Bard? 112:1 A. Yes. 112:2 Q. Okay. So you were -- you were the sales 112:3 representative that interacted with Dr. Avino? 112:4 A. I was one of the sales reps that interacted 112:5 with Dr. Avino, yes. 112:6 Q. In 2010 was there another sales 112:7 representative that interacted with Dr. Avino?	Sussman_COMBO_0524_R02.37

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112:8 A. No.

112:9 Q. And do you --

112:10 A. Not with our division, not in regard to IVC

112:11 filters.

112:12 Q. Do you -- do you have a social

112:13 relationship in -- did -- at the time that you were a

112:14 sales representative for Bard, did you have a social

112:15 relationship with Dr. Avino as well as a professional

112:16 relationship?

112:17 A. Yes.

112:18 Q. Okay. And what was the nature of the social

112:19 relationship?

112:20 A. Our kids are on the same baseball team.

112:21 He's, as you mentioned, a partner in my husband's

112:22 practice, so we certainly had -- we -- we were

112:23 certainly friendly.

112:24 Q. Okay. Did you socialize together, go to

112:25 dinners together?

113:1 A. Yes.

114:16 - 115:11

Sussman, Melanie 04-07-2017 (00:00:42)

Sussman_COMBO_0524_R02.38

114:16 Q. Do you have any independent knowledge, other

114:17 than discussions with counsel, regarding Mrs. Jones'

114:18 case?

114:19 A. No.

114:20 Q. Did you discuss it with Dr. Avino at all?

114:21 A. No.

114:22 Q. Did you discuss it with Dr. Nelson?

114:23 A. No.

114:24 Q. Okay. And that's Dr. Kristin Nelson?

114:25 A. Kirstin.

115:1 Q. Kirstin. Okay. Oh, it's -- yeah, Kirstin.

115:2 A. Everybody makes that mistake.

115:3 Q. And is she also a partner with your husband?

115:4 A. She is.

115:5 Q. Okay. And do you social -- do you have both

115:6 a professional and social relationship with her as

115:7 well?

115:8 A. Yes, somewhat.

115:9 Q. What's the nature of the social relationship?

115:10 A. I would say mainly holiday dinners and that

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142:2 - 142:6	<p>115:11 kind of thing with the practice.</p> <p>Sussman, Melanie 04-07-2017 (00:00:09)</p> <p>142:2 Have you seen this document before?</p> <p>142:3 A. No.</p> <p>142:4 Q. Do you know what a Remedial Action Plan is?</p> <p>142:5 A. I could make a speculation but I don't know</p> <p>142:6 in this instance, no.</p>	Sussman_COMBO_0524_R02.41
168:22 - 169:1	<p>Sussman, Melanie 04-07-2017 (00:00:13)</p> <p>168:22 Q. Are you familiar with electropolishing?</p> <p>168:23 A. Somewhat, yes.</p> <p>168:24 Q. What's your understanding of</p> <p>168:25 electropolishing?</p> <p>169:1 A. It smooths the finish of the Nitinol.</p>	Sussman_COMBO_0524_R02.43
178:14 - 178:17	<p>Sussman, Melanie 04-07-2017 (00:00:07)</p> <p>178:14 Q. Okay. And again, we discussed the Eclipse</p> <p>178:15 filter is essentially the G2 or G2X with</p> <p>178:16 electropolishing, correct?</p> <p>178:17 A. Yes.</p>	Sussman_COMBO_0524_R02.44
185:12 - 185:12	<p>Sussman, Melanie 04-07-2017 (00:00:00)</p> <p>185:12 (Exhibit 2139 was marked for identification.)</p>	Sussman_COMBO_0524_R02.45
186:16 - 186:18	<p>Sussman, Melanie 04-07-2017 (00:00:07)</p> <p>186:16 Q. And what's the difference between the</p> <p>186:17 Meridian filter and the Eclipse filter?</p> <p>186:18 A. The Meridian has anchors on its feet.</p>	Sussman_COMBO_0524_R02.46
191:11 - 191:11	<p>Sussman, Melanie 04-07-2017 (00:00:01)</p> <p>191:11 A. That was my understanding.</p>	Sussman_COMBO_0524_R02.53
191:12 - 191:15	<p>Sussman, Melanie 04-07-2017 (00:00:12)</p> <p>191:12 Q. Okay. And did you ever at any time have any</p> <p>191:13 discussions with any of your physicians that the</p> <p>191:14 Eclipse was the same as the G2X and could be expected</p> <p>191:15 to essentially perform the same as the G2X?</p>	Sussman_COMBO_0524_R02.54
191:17 - 191:20	<p>Sussman, Melanie 04-07-2017 (00:00:14)</p> <p>191:17 A. Again, I can't really make any -- any</p> <p>191:18 guarantees on a product. I made my physicians aware</p> <p>191:19 that we had electropolished the filter in hopes to</p> <p>191:20 continue improvement.</p>	Sussman_COMBO_0524_R02.55
239:9 - 240:10	<p>Sussman, Melanie 04-07-2017 (00:01:25)</p> <p>239:9 Can you tell me anything you recall</p> <p>239:10 discussing with Dr. Avino about the Eclipse filter</p> <p>239:11 prior to August of 2010?</p>	Sussman_COMBO_0524_R02.62

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239:12 A. Yes.

239:13 Q. Okay. What do you recall?

239:14 A. I don't recall any specifics but I am certain

239:15 I talked to him about the features and benefits of

239:16 the filter, and I'm sure we even placed some filters

239:17 together, but I -- I don't recall any specifics.

239:18 Q. Do you recall any specifics of the features

239:19 and benefits you might have discussed with Dr. Avino

239:20 with respect to the Eclipse filter prior to August of

239:21 2010?

239:22 A. I can make a -- I can make an educated guess,

239:23 yes.

239:24 Q. Well, no, no. I want to know if you can

239:25 recall this. I don't want you to guess.

240:1 A. I can't recall any specifics.

240:2 Q. Yeah. So -- so you have a -- let me -- let

240:3 me ask another question.

240:4 You have no specific -- is it correct that

240:5 you have no specific recollection of a specific

240:6 conversation with Dr. Avino about the Eclipse?

240:7 A. I had conversations with him talking about

240:8 the filter's introduction and the features and

240:9 benefits. I do not recall the specifics of the

240:10 conversation.

243:23 - 244:17

Sussman, Melanie 04-07-2017 (00:01:22)

Sussman_COMBO_0524_R02.64

243:23 about here today, but did you recall generally having

243:24 conversations with Dr. Avino about the G2 filter?

243:25 A. No specifics.

244:1 Q. Okay. Do you have any similar general

244:2 recollections of having conversations with Dr. Avino

244:3 about the features and benefits of the G2 filter?

244:4 A. Again, I can't -- I couldn't tell you

244:5 verbatim what I talked to him that many years ago,

244:6 but I know I would have talked to him about any

244:7 improvements that we had made over prior generations

244:8 and what might be new about the delivery system and

244:9 what he might expect.

244:10 Q. Now, when you talk about benefits to the

244:11 filter, what kind of things would you have been talking

244:12 about, to the best of your recollection?

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244:13 A. Ease of deployment, low -- the profile of the
 244:14 delivery system, where they might gain access with
 244:15 the patients, caval size that they -- that were
 244:16 recommended, and the IFUs that were associated with
 244:17 the device.

247:6 - 247:19

Sussman, Melanie 04-07-2017 (00:00:38)

Sussman_COMBO_0524_R02.67

247:6 Did you discuss with him any of the
 247:7 complications -- any complications for the Eclipse
 247:8 filter other than what are in the IFU for that filter?
 247:9 A. I did not discuss with him any risks or
 247:10 complications of the Eclipse filter beyond normal
 247:11 inherent risks and complications.
 247:12 Q. And is there a distinction that you've drawn
 247:13 there between normal inherent complications and what
 247:14 is in the IFU?
 247:15 A. No.
 247:16 Q. So is it fair to say then that you didn't
 247:17 discuss with him any complications that are not set
 247:18 forth in the IFU?
 247:19 A. True.

247:23 - 249:11

Sussman, Melanie 04-07-2017 (00:01:49)

Sussman_COMBO_0524_R02.69

247:23 Q. Did you ever discuss with him the risk of
 247:24 this particular filter having a fracture and a
 247:25 fragment of that filter migrating through the
 248:1 patient's heart and into the pulmonary artery?
 248:2 A. He was -- again, I think he was well aware of
 248:3 those risks.
 248:4 Q. That's -- again, ma'am, I apologize if I'm
 248:5 not clear but my question isn't about what Dr. Avino
 248:6 knew. It's about what you told him and what you
 248:7 discussed with him.
 248:8 A. Right.
 248:9 Q. Do you understand the difference between
 248:10 those two things?
 248:11 A. I believe I understand.
 248:12 Q. Okay. So my question again is did you have a
 248:13 discussion with Dr. Avino regarding the risk of this
 248:14 particular filter having a fracture and a fragment of
 248:15 the filter migrating through the patient's heart and
 248:16 into the pulmonary artery?

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	248:17 A. I believe we did have conversations in regard 248:18 to the inherent risks of all filters, and I know 248:19 that's not your question, but it was inclusive of the 248:20 Eclipse filter, yes. 248:21 Q. Did you have a conversation about that 248:22 specific risk, of a fracture and a fragment of the 248:23 filter migrating through the heart and into the 248:24 pulmonary artery? 248:25 A. We probably did, yes. 249:1 Q. And how -- is that a routine conversation you 249:2 have with doctors about potential risks of a filter? 249:3 A. In general terms, yes. 249:4 Q. And what do you mean by in general terms? 249:5 A. Risks and benefits of any -- risks and 249:6 complications of any device that we have on the 249:7 market they're well aware of, and as we all know, 249:8 they're in the IFUs and they are well known. 249:9 Q. Well, there is nothing, ma'am, in the IFU 249:10 that says a filter piece may break off and migrate 249:11 into your pulmonary artery, is there?	
249:13 - 249:18	Sussman, Melanie 04-07-2017 (00:00:16) 249:13 A. I have actually witnessed Dr. Avino talking 249:14 to patients, telling them each of those specific 249:15 risks in regard to a filter. I've actually witnessed 249:16 him saying filter fracture, even death, is an 249:17 unfortunate but rare complication of any filters on 249:18 the market.	Sussman_COMBO_0524_R02.70
251:24 - 252:6	Sussman, Melanie 04-07-2017 (00:00:26) 251:24 Q. Okay. Now, would you agree with me that 251:25 there -- there are differences between the various 252:1 devices in the market in terms of the rate at which 252:2 they suffer those adverse events? 252:3 A. I don't think you can make those comparisons. 252:4 Q. And on what do you base that? 252:5 A. I have never seen true data that actually can 252:6 make those comparisons. If you have it, please show	Sussman_COMBO_0524_R02.71
264:6 - 264:12	Sussman, Melanie 04-07-2017 (00:00:20) 264:6 Q. So in your role of trying to be a trusted 264:7 advisor to your doctors about the filters you were 264:8 selling, did you go out and review peer-reviewed	Sussman_COMBO_0524_R02.77

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264:9 literature to see what the potential complication --
 264:10 not potential, but what the complication rates were
 264:11 for your products as being experienced by doctors in
 264:12 the field?

264:14 - 265:19

Sussman, Melanie 04-07-2017 (00:01:38)

Sussman_COMBO_0524_R02.78

264:14 A. Again, I don't -- I don't think you can
 264:15 ascertain those numbers.
 264:16 Q. So you -- so you didn't do that then?
 264:17 A. I have looked at lots and lots of different
 264:18 articles. I have watched physicians dissect them
 264:19 during journal clubs. I have seen copies of them,
 264:20 reads copies of them, yes, but data can be skewed in
 264:21 any number of various ways and I don't think that
 264:22 there are any head-to-head studies out there that are
 264:23 reliable. I don't think the data is available. It's
 264:24 unfortunate. I wish -- I wish it were.
 264:25 Q. And your testimony that it's not reliable is
 265:1 based on what expertise?
 265:2 A. As I told you, I don't have any statistics
 265:3 background, I don't have a medical degree, none of
 265:4 that. I just know that from -- and especially
 265:5 talking to physicians, there is no reliable
 265:6 head-to-head study out there.
 265:7 Q. And is it your testimony the only way to make
 265:8 the determination of relative failure rates is a
 265:9 head-to-head study?
 265:10 A. If you're going to make comparisons on the
 265:11 mark -- in the market.
 265:12 Q. What's your basis for that?
 265:13 A. How could you possibly do that? Do you know
 265:14 every filter that was ever sold from every
 265:15 manufacturer out there? Do you know how many were
 265:16 implanted, how many are still sitting on the shelf,
 265:17 how many were reported, not reported? I don't -- I
 265:18 don't -- there are so many different factors, I just
 265:19 don't think it's ever plausible.

266:17 - 266:20

Sussman, Melanie 04-07-2017 (00:00:11)

Sussman_COMBO_0524_R02.79

266:17 Q. Okay. And what information did you use
 266:18 competitively when you were addressing your doctors to
 266:19 talk about the Cordis filter, the Cook filter, and the

Sussman_COMBO_0524_R02

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266:22 - 267:11	<p>266:20 VenaTech filter?</p> <p>Sussman, Melanie 04-07-2017 (00:00:55)</p> <p>266:22 A. The only -- I mean, the only thing we could</p> <p>266:23 really talk about was what was important to them in</p> <p>266:24 terms of making the delivery and whether it was -- a</p> <p>266:25 lot of times it was ease of use. Unfortunately,</p> <p>267:1 physicians brought up price a lot more recently.</p> <p>267:2 That was not something I liked to focus on, but</p> <p>267:3 usually it was an ease of use, it was -- they</p> <p>267:4 certainly talked about their own history and</p> <p>267:5 experience with our filter and other filters. So I</p> <p>267:6 would --</p> <p>267:7 Q. Did you talk with any of your doctors about</p> <p>267:8 comparative rates of complications with those devices?</p> <p>267:9 A. Unfortunately, or fortunately, my physicians</p> <p>267:10 don't really rely on sales reps to give them that</p> <p>267:11 data.</p>	Sussman_COMBO_0524_R02.80
268:8 - 268:13	<p>Sussman, Melanie 04-07-2017 (00:00:18)</p> <p>268:8 Q. And do you recall any of those various</p> <p>268:9 presentations you had making comparative claims with</p> <p>268:10 respect to the various filters, that Bard had lower</p> <p>268:11 complication rates or was more fracture resistant or</p> <p>268:12 was more migration resistant than a competitive</p> <p>268:13 filter?</p>	Sussman_COMBO_0524_R02.81
268:15 - 268:16	<p>Sussman, Melanie 04-07-2017 (00:00:03)</p> <p>268:15 A. I don't believe we could make those</p> <p>268:16 comparisons.</p>	Sussman_COMBO_0524_R02.82
276:14 - 276:17	<p>Sussman, Melanie 04-07-2017 (00:00:07)</p> <p>276:14 Q. And this is Matthew Lerner, for the record.</p> <p>276:15 Ms. Sussman, I know it's been a long day, so</p> <p>276:16 I'm just going to ask you just a few additional</p> <p>276:17 questions.</p>	Sussman_COMBO_0524_R02.83
276:21 - 277:11	<p>Sussman, Melanie 04-07-2017 (00:00:33)</p> <p>276:21 Q. Okay. And you have two children?</p> <p>276:22 A. Two children.</p> <p>276:23 Q. And how old are they?</p> <p>276:24 A. My son just turned 12 and my daughter just</p> <p>276:25 turned nine.</p> <p>277:1 Q. And you live in the Savannah area?</p> <p>277:2 A. Yes.</p>	Sussman_COMBO_0524_R02.84

Sussman_COMBO_0524_R02

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277:3 Q. Okay. And I know we've talked a lot today
277:4 about things dating back to 2000. We're in March of
277:5 2017 -- I'm sorry, April of 2017.

277:6 A. That is correct, yes.

277:7 Q. All right. And so in answering questions
277:8 today, did you, given your medical condition and the
277:9 years, did you try to respond to the best of your
277:10 memory?

277:11 A. To the best of my ability, yes.

278:3 - 278:7

Sussman, Melanie 04-07-2017 (00:00:11)

Sussman_COMBO_0524_R02.85

278:3 Q. Let's talk a little bit about your experience
278:4 at Bard. How would you describe your experiences
278:5 working for Bard over the years?

278:6 A. It was very good, very good experience. No
278:7 problem. It was wonderful.

278:12 - 278:23

Sussman, Melanie 04-07-2017 (00:00:25)

Sussman_COMBO_0524_R02.86

278:12 If physicians had any concerns about the
278:13 products that you were -- that were sort of in your
278:14 bag that you were selling, would you address those
278:15 concerns with physicians?

278:16 A. Absolutely.

278:17 Q. And then as a role -- in your role as a sales
278:18 representative, did you ever work within the research
278:19 and design department?

278:20 A. No, sir.

278:21 Q. Okay. So were you ever responsible for the
278:22 design of any products?

278:23 A. No.

279:4 - 279:9

Sussman, Melanie 04-07-2017 (00:00:10)

Sussman_COMBO_0524_R02.87

279:4 Q. Were you responsible for tracking and
279:5 trending and analyzing those adverse events?

279:6 A. No, sir.

279:7 Q. Was there a department at Bard that was
279:8 responsible for doing that?

279:9 A. Yes.

279:11 - 279:18

Sussman, Melanie 04-07-2017 (00:00:28)

Sussman_COMBO_0524_R02.88

279:11 First, when you were
279:12 at Bard, how many different products did you have in
279:13 your bag, so to speak?

279:14 A. It varied. When I first started, I probably

Sussman_COMBO_0524_R02

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279:24 - 280:5	<p>279:15 had eight or ten, and when I left I would say -- I 279:16 mean, there were about eight different product 279:17 categories, but then subcategories, we had, oh, 279:18 goodness, dozens.</p> <p>Sussman, Melanie 04-07-2017 (00:00:15)</p> <p>279:24 Q. So for the dozens of products that you had in 279:25 your -- your products -- any time that Bard received 280:1 an adverse event relating to those products, was it 280:2 your expectation that any time there was an adverse 280:3 event relating to any of the products in your bag, 280:4 that you would get some notification of that? 280:5 A. Oh, no. I wouldn't have gotten my job done.</p>	Sussman_COMBO_0524_R02.89
283:16 - 283:24	<p>Sussman, Melanie 04-07-2017 (00:00:21)</p> <p>283:16 Q. Okay. Roughly, what percentage of your 283:17 portfolio of products was made up of IVC filters 283:18 compared to other products? 283:19 A. In our bag, probably 10 to 15 percent. 283:20 Q. Okay. And then what percentage of your time 283:21 in meeting with physicians did you spend with visiting 283:22 physicians about IVC filters as compared to other 283:23 products? 283:24 A. Approximately the same percentage.</p>	Sussman_COMBO_0524_R02.90
284:12 - 284:24	<p>Sussman, Melanie 04-07-2017 (00:00:33)</p> <p>284:12 Q. When you were -- when you were selling the 284:13 Bard IVC filters, the optional filters, did you 284:14 believe in those products? 284:15 A. Absolutely. 284:16 Q. Did you believe they were important products 284:17 to be on the market? 284:18 A. Yes. 284:19 Q. And why is that? 284:20 A. They were life-saving devices. These -- we 284:21 actually had the first optional filter to market, 284:22 which was revolutionary and physicians were ecstatic 284:23 and it was -- it's just -- I absolutely believed in 284:24 our products.</p>	Sussman_COMBO_0524_R02.91
285:5 - 285:12	<p>Sussman, Melanie 04-07-2017 (00:00:18)</p> <p>285:5 Q. And did you ever try to downplay 285:6 complications with Bard's filters with doctors in the 285:7 Savannah area?</p>	Sussman_COMBO_0524_R02.92

Sussman_COMBO_0524_R02

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285:8 A. No.

285:9 Q. With any of your doctors that were in your

285:10 territories, did you ever try to downplay

285:11 complications?

285:12 A. Not at all.

285:22 - 287:12

Sussman, Melanie 04-07-2017 (00:01:54)

Sussman_COMBO_0524_R02.03

285:22 Q. And so when complications happened in your

285:23 territory, did you make any effort to kind of hide

285:24 those complications or to downplay those

285:25 conversations?

286:1 A. Not at all.

286:2 Q. And why not?

286:3 A. There was -- there was no reason to.

286:4 Q. Based on your experience with talking with

286:5 doctors in your community, in the Savannah community,

286:6 were the risks of complications like perforation,

286:7 fracture, migration, inability to retrieve a filter,

286:8 were those complications generally known in your

286:9 community?

286:10 A. Yes.

286:11 Q. And with each filter that's sold, are they

286:12 accompanied by an Instructions For Use?

286:13 A. Yes.

286:14 Q. Okay. So each of the Eclipse filters that

286:15 were sold would have had an Instructions For Use with

286:16 it?

286:17 A. They did, yes.

286:18 Q. And those would have included various

286:19 complications?

286:20 A. Absolutely.

286:21 Q. And without naming specific medical

286:22 literature, are you aware of any medical literature

286:23 that discusses complications of IVC filters, including

286:24 Bard's filters, before 2010?

286:25 A. Yes.

287:1 Q. There was some discussion today about the

287:2 fact that Dr. Avino practices with your husband.

287:3 A. That's correct.

287:4 Q. Do you think that would make your job easier

287:5 or harder?

PL

DEF

Sussman_COMBO_0524_R02

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287:6 A. It was infinitely harder. They held me to a
 287:7 much higher standard. The hospital did as well, and
 287:8 I was extremely forthright with them, as I mentioned
 287:9 earlier, told them about any complications that any
 287:10 other accounts might have. I -- it was -- it was
 287:11 almost -- it was probably twice as hard to do my job
 287:12 because of that relationship.

287:19 - 288:3

Sussman, Melanie 04-07-2017 (00:00:21)

Sussman_COMBO_0524_R02.24

287:19 Q. Mrs. Sussman, is it fair to say in your
 287:20 dealing with doctors, that if you had information, you
 287:21 were forthright and you gave it to them?

287:22 A. If I had information that they would want to
 287:23 know and that was reliable, then yes.

287:24 Q. And if you didn't have information, you
 287:25 couldn't give it to them, right?

288:1 A. If I didn't have information, I couldn't give
 288:2 it to them.

288:3 MR. STOLLER: Thank you.

PL = 00:04:26

DEF = 00:29:00

Total Time = 00:33:26

PL

DEF

Exhibit Q

Designation Run Report

Trerotola (Jones)

Trerotola, Scott 01-20-2017

Plaintiff Designations 00:02:33

Bard Designations 00:08:43

Total Time 00:11:16



Trerotola_COMBO_R01-Trerotola (Jones)

Page/Line	Source	ID
5:24 - 6:2	Trerotola, Scott 01-20-2017 (00:00:04) 5:24 Would you please state your name for the 6:1 record, please. 6:2 A. Scott Trerotola.	Trerotola_COMBO_R01.1
7:23 - 8:10	Trerotola, Scott 01-20-2017 (00:00:22) 7:23 Q. The deposition here today, I understand 7:24 that you have been a consultant for Bard; is that 8:1 correct? 8:2 A. That is correct. 8:3 Q. Are you still a consultant with Bard? 8:4 A. Yes, I am. 8:5 Q. How long have you been a consultant for 8:6 Bard? 8:7 A. Since sometime in the 1990s. 8:8 Q. Do you currently have a consulting 8:9 agreement? 8:10 A. Yes, I do.	Trerotola_COMBO_R01.32
8:17 - 8:18	Trerotola, Scott 01-20-2017 (00:00:02) 8:17 Q. And are you paid for that? 8:18 A. I am.	Trerotola_COMBO_R01.33
8:22 - 8:24	Trerotola, Scott 01-20-2017 (00:00:04) 8:22 Q. What is the hourly rate that you charge 8:23 Bard for consulting? 8:24 A. \$500.	Trerotola_COMBO_R01.34
9:24 - 10:3	Trerotola, Scott 01-20-2017 (00:00:06) 9:24 Q. Do you consult with any other type -- 10:1 any other medical device company? 10:2 A. I do consult with other medical device 10:3 companies, yes.	Trerotola_COMBO_R01.2
16:4 - 16:7	Trerotola, Scott 01-20-2017 (00:00:06) 16:4 Q. Have you served as an expert for Bard? 16:5 A. An expert witness? 16:6 Q. Yes. 16:7 A. I don't think so.	Trerotola_COMBO_R01.3
19:7 - 19:14	Trerotola, Scott 01-20-2017 (00:00:20) 19:7 Physicians rely on the company that 19:8 sells devices among other avenues to provide 19:9 information about safety of the device, correct? 19:10 A. I would disagree with that. 19:11 Q. Why?	Trerotola_COMBO_R01.4

Trerotola_COMBO_R01-Trerotola (Jones)

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19:12 A. Physicians generally rely on the medical
19:13 literature to learn about their devices and their
19:14 products they're going to use.

20:6 - 20:9

Trerotola, Scott 01-20-2017 (00:00:08)

Trerotola_COMBO_R01.5

20:6 Q. Have you implanted Bard filters?

20:7 A. I have.

20:8 Q. Do you currently implant filters?

20:9 A. Yes.

22:24 - 23:6

Trerotola, Scott 01-20-2017 (00:00:16)

Trerotola_COMBO_R01.6

22:24 Q. Well, as a physician, do you expect that
23:1 any information you receive from a company about a
23:2 medical device will be factually accurate and truthful?

23:3 A. Actually, I don't expect that.

23:4 Q. You don't?

23:5 A. I take the brochures and throw them in
23:6 the trash.

23:14 - 23:21

Trerotola, Scott 01-20-2017 (00:00:23)

Trerotola_COMBO_R01.7

23:14 Q. Do you agree that a company should, when
23:15 it provides information, promotional information about
23:16 its product, be factually accurate in that writing?
23:17 A. That's not for me to say. For me as a
23:18 physician, my belief is that I'm going to read the
23:19 medical literature, I'm going to use my own experience
23:20 and judge for myself as to whether I am going to use a
23:21 device or not.

31:17 - 31:24

Trerotola, Scott 01-20-2017 (00:00:24)

Trerotola_COMBO_R01.8

31:17 Q. I mean, have you ever relied on anything
31:18 a sales representative from Bard told you about a
31:19 medical device, such as a filter?
31:20 A. I could tell you that everything that I
31:21 do with a device, I find independently. I'll read the
31:22 instructions for use, which are something that's just
31:23 been specifically, you know, cleared by the FDA. Like
31:24 I said, the brochures, they go in the trash.

35:17 - 35:23

Trerotola, Scott 01-20-2017 (00:00:15)

Trerotola_COMBO_R01.41

35:17 Q. Well, you know that you are here because
35:18 you are a consultant for Bard, correct?

35:19 A. That's correct.

35:20 Q. And you have consulted with Bard on
35:21 filters, correct?

Trerotola_COMBO_R01-Trerotola (Jones)

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35:22 A. Part of my consulting for Bard is with
35:23 filters.

54:6 - 54:12

Trerotola, Scott 01-20-2017 (00:00:17)

Trerotola_COMBO_R01.9

54:6 Q. Do you understand that optional means
54:7 that the filter is permanent and can also be optionally
54:8 retrieved?

54:9 A. Actually, I don't -- that's not my
54:10 understanding. I would say it the other way around. I
54:11 would say that the filter is meant to be retrieved but
54:12 can remain permanent, if desired.

77:11 - 77:16

Trerotola, Scott 01-20-2017 (00:00:18)

Trerotola_COMBO_R01.10

77:11 Q. Was a feature of the retrievable filter
77:12 the ease of removing the filter?

77:13 A. I wouldn't say that somebody was saying
77:14 the ease of removal, I would say the feature -- the
77:15 attractive feature to us as practicing clinicians was
77:16 the ability to retrieve the filter.

78:8 - 78:11

Trerotola, Scott 01-20-2017 (00:00:12)

Trerotola_COMBO_R01.11

78:8 Q. And the difficult retrievals may be the
78:9 result of different types of complications experienced
78:10 by the filter while it's in the patient?

78:11 A. That's correct.

80:2 - 80:10

Trerotola, Scott 01-20-2017 (00:00:18)

Trerotola_COMBO_R01.12

80:2 Q. But when it penetrates through the vena
80:3 cava wall, that does lead to a difficult retrieval,
80:4 using your words?

80:5 A. I didn't say that, no. I absolutely did
80:6 not say that.

80:7 Q. Is that a -- can that be a feature of a
80:8 difficult retrieval?

80:9 A. Penetration of itself is not really a
80:10 feature of difficult retrieval.

83:16 - 83:18

Trerotola, Scott 01-20-2017 (00:00:07)

Trerotola_COMBO_R01.13

83:16 Q. And then when the G2 was launched, were
83:17 you using the majority of your optional filters the G2?

83:18 A. Yes.

92:1 - 92:12

Trerotola, Scott 01-20-2017 (00:00:33)

Trerotola_COMBO_R01.45

92:1 Q. Recovery fractures that you were hearing

92:2 about --

92:3 A. Yeah.

Trerotola_COMBO_R01-Trerotola (Jones)

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92:4 Q. -- understanding they were different
 92:5 than your personal experience, did that, among other
 92:6 things, cause a concern for patient safety?
 92:7 A. That made us pay attention.
 92:8 Q. And did you pay attention, among the
 92:9 reasons that you paid attention, were in the interest
 92:10 of patient safety, among other reasons?
 92:11 A. Certainly, we would be concerned about a
 92:12 fracture for safety, sure. Yes, I do say that.

93:4 - 93:7

Trerotola, Scott 01-20-2017 (00:00:12)

Trerotola_COMBO_R01.14

93:4 Q. And your understanding was that Bard was
 93:5 putting the G2 out there as with improved features that
 93:6 would, among other things, resist fracture?
 93:7 A. That was my understanding, yes.

93:8 - 93:11

Trerotola, Scott 01-20-2017 (00:00:08)

Trerotola_COMBO_R01.46

93:8 Q. Were you aware of problems with Recovery
 93:9 tilting?
 93:10 A. We had personally seen problems with
 93:11 Recovery tilting, yes.

93:12 - 94:2

Trerotola, Scott 01-20-2017 (00:00:47)

Trerotola_COMBO_R01.15

93:12 Q. And when Bard launched the G2, did Bard
 93:13 indicate to you that the G2 had improved centering and
 93:14 stability?
 93:15 A. In the course of my consulting with
 93:16 Bard, we had discussions about the design changes, and
 93:17 one of the goals was to try to reduce tilting, yes.
 93:18 Q. And that's what Bard had indicated that
 93:19 they were -- was the intent behind the G2, to make an
 93:20 improvement, tilt resistance over the Recovery?
 93:21 A. I'm not sure that -- I can't speak to
 93:22 what Bard's intention was. My understanding was that
 93:23 there were two improvements. One was that the arms
 93:24 were longer and the little sort of indentations on the
 94:1 end to keep the legs, arms from poking in, which
 94:2 supposedly would reduce fracture, would reduce tilting.

94:23 - 95:7

Trerotola, Scott 01-20-2017 (00:00:26)

Trerotola_COMBO_R01.16

94:23 Q. Did you ever talk to Bard about its
 94:24 experience with tilting, whether it had -- could advise
 95:1 you as to how many incidents or events they were aware
 95:2 of at Bard that involve tilting?

Trerotola_COMBO_R01-Trerotola (Jones)

Page/Line	Source	ID
95:3 - 95:20	<p>95:3 A. To be honest, I don't think we would</p> <p>95:4 have had that conversation, because tilting is a common</p> <p>95:5 enough problem with all kinds of filters that that's</p> <p>95:6 not really a conversation I would think we would have,</p> <p>95:7 but I don't know for sure.</p> <p>Trerotola, Scott 01-20-2017 (00:00:06)</p> <p>95:18 Q. Is it possible that the G2 became your</p> <p>95:19 exclusive optional filter?</p> <p>95:20 A. Yes.</p>	Trerotola_COMBO_R01.17
98:19 - 98:21	<p>Trerotola, Scott 01-20-2017 (00:00:05)</p> <p>98:19 Q. And for what reasons?</p> <p>98:20 A. Because an alternative filter became</p> <p>98:21 available.</p>	Trerotola_COMBO_R01.18
99:4 - 99:7	<p>Trerotola, Scott 01-20-2017 (00:00:08)</p> <p>99:4 A. Yeah, I think there were some</p> <p>99:5 discussions about G2 migration, but we're not talking</p> <p>99:6 about big migration. I think a lot of people</p> <p>99:7 misconstrue, misuse the word migration.</p>	Trerotola_COMBO_R01.19
99:15 - 99:21	<p>Trerotola, Scott 01-20-2017 (00:00:16)</p> <p>99:15 Q. What was the issue about migration and</p> <p>99:16 G2 that you had talked to other doctors about?</p> <p>99:17 A. That it appeared to have a tendency to</p> <p>99:18 move downward a little bit.</p> <p>99:19 Q. Did you call that caudal migration?</p> <p>99:20 A. That would be termed caudal migration,</p> <p>99:21 yeah.</p>	Trerotola_COMBO_R01.48
102:12 - 102:18	<p>Trerotola, Scott 01-20-2017 (00:00:26)</p> <p>102:12 Q. Is caudal migration an indication that</p> <p>102:13 the filter is not remaining stable?</p> <p>102:14 A. I'm going to rephrase to say that the</p> <p>102:15 caudal migration is an indication that at some point</p> <p>102:16 the filter moved. You said remaining unstable. That's</p> <p>102:17 different. The filter moved, but then once it moves,</p> <p>102:18 it may stay there.</p>	Trerotola_COMBO_R01.20
105:18 - 105:21	<p>Trerotola, Scott 01-20-2017 (00:00:12)</p> <p>105:18 Q. And you indicated that an issue with</p> <p>105:19 penetration is that it could lead to tilt?</p> <p>105:20 A. Actually, penetration probably reduces</p> <p>105:21 tilt, in my opinion. That's only my opinion.</p>	Trerotola_COMBO_R01.21
119:15 - 119:18	<p>Trerotola, Scott 01-20-2017 (00:00:10)</p>	Trerotola_COMBO_R01.22

Trerotola_COMBO_R01-Trerotola (Jones)

Page/Line	Source	ID
119:15 Q. Would that be the reason you didn't 119:16 adopt -- I mean, it sounds to me like if you had your 119:17 option, you're going to stay with the G2? 119:18 A. We really liked the G2.		
125:16 - 125:22	Trerotola, Scott 01-20-2017 (00:00:24) 125:16 Q. Well, if Bard had indicated to you, for 125:17 example, that they were making a filter, like when the 125:18 G2 came out, that was going to be resistant to fracture 125:19 and some of the problems that the Recovery had 125:20 experienced, you would expect Bard to test that model 125:21 to know that the filter could, in fact, do what they 125:22 said it was going to do?	Trerotola_COMBO_R01.23
125:24 - 126:5	Trerotola, Scott 01-20-2017 (00:00:10) 125:24 THE WITNESS: So I would expect Bard to 126:1 test that model, however, you said "know." 126:2 Nobody can know what's going to happen. You 126:3 can do all the testing in the world, you're 126:4 never going to be able to predict what's going 126:5 to happen in a human being.	Trerotola_COMBO_R01.24
126:7 - 126:18	Trerotola, Scott 01-20-2017 (00:00:33) 126:7 Q. Well, what's your understanding of the 126:8 purpose of testing? 126:9 A. The purpose of testing is to get to -- 126:10 as close as possible to, you know, knowing, but you're 126:11 never going to know, but to try to simulate the 126:12 condition the filter is going to be in and, hopefully, 126:13 get it to perform in the way you want it to perform. I 126:14 mean, that's sort of a loosely construed sort of 126:15 layman's. 126:16 Q. So you would expect Bard to test the G2 126:17 filter to determine whether it was improved over the 126:18 Recovery?	Trerotola_COMBO_R01.25
126:20 - 126:21	Trerotola, Scott 01-20-2017 (00:00:03) 126:20 THE WITNESS: My understanding was that 126:21 such testing was done.	Trerotola_COMBO_R01.26
126:23 - 127:5	Trerotola, Scott 01-20-2017 (00:00:22) 126:23 Q. And that's something that you, as a 126:24 doctor, would expect that would be done, correct? 127:1 A. Speaking as a physician and as a user of 127:2 medical devices, it would be my hope that and my	Trerotola_COMBO_R01.54

Trerotola_COMBO_R01-Trerotola (Jones)

Page/Line	Source	ID
129:6 - 129:9	<p>127:3 expectation that somebody presenting a device that is 127:4 expected to address a prior concern would have tested 127:5 that, yes.</p> <p>Trerotola, Scott 01-20-2017 (00:00:05)</p> <p>129:6 Q. Were you aware that Dr. Asch had told 129:7 Bard that he had safety concerns regarding the Recovery 129:8 filter? 129:9 A. No.</p>	Trerotola_COMBO_R01.57
129:17 - 129:19	<p>Trerotola, Scott 01-20-2017 (00:00:11)</p> <p>129:17 Q. Were you aware that Dr. Asch had told 129:18 Bard that the safety concern should be improved before 129:19 placing the filter on the market?</p>	Trerotola_COMBO_R01.58
129:21 - 129:22	<p>Trerotola, Scott 01-20-2017 (00:00:01)</p> <p>129:21 THE WITNESS: I don't recall hearing 129:22 that.</p>	Trerotola_COMBO_R01.59
135:12 - 135:14	<p>Trerotola, Scott 01-20-2017 (00:00:06)</p> <p>135:12 Q. And doctors have expressed to you 135:13 concerns that they had about the Recovery in terms of 135:14 the failures they were seeing?</p>	Trerotola_COMBO_R01.27
135:16 - 135:22	<p>Trerotola, Scott 01-20-2017 (00:00:19)</p> <p>135:16 THE WITNESS: You know, this is a long 135:17 time ago, back, you know, when you're talking 135:18 about them, I mean, we talk about problems with 135:19 filters all the time, including now. Can I 135:20 tell you exactly whether a doctor came to me 135:21 and said I'm concerned about this, it might 135:22 have happened. I don't know.</p>	Trerotola_COMBO_R01.28
177:11 - 177:13	<p>Trerotola, Scott 01-20-2017 (00:00:05)</p> <p>177:11 Q. Meaning that if they're used as a 177:12 permanent filter, they should last the life of the 177:13 patient?</p>	Trerotola_COMBO_R01.29
177:18 - 177:23	<p>Trerotola, Scott 01-20-2017 (00:00:12)</p> <p>177:18 regulatory pathway went. That's not to say that they 177:19 were ever intended to be permanent filters. Our intent 177:20 as doctors using these was not to use them as permanent 177:21 filters. And if you look at everything I've ever 177:22 written on this subject, that's completely consistent 177:23 with what I'm saying.</p>	Trerotola_COMBO_R01.70
178:20 - 179:3	<p>Trerotola, Scott 01-20-2017 (00:00:20)</p> <p>178:20 Q. Were you aware that the Simon Nitinol</p>	Trerotola_COMBO_R01.30

Trerotola_COMBO_R01-Trerotola (Jones)

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178:21 filter, according to Bard, virtually had no complaints
 178:22 associated with it?
 178:23 A. That I would strongly disagree with that
 178:24 statement. We really thought the Nitinol -- we
 179:1 actually called it the Frightenol. We thought it was
 179:2 not a good filter and didn't use it. These are the
 179:3 doctors in the community.

179:4 - 179:7

Trerotola, Scott 01-20-2017 (00:00:07)

Trerotola_COMBO_R01.68

179:4 Q. Did you ever ask Bard the number of
 179:5 complaints they had with the Simon Nitinol?
 179:6 A. I had no reason to. I didn't use the
 179:7 filter.

195:11 - 196:2

Trerotola, Scott 01-20-2017 (00:00:40)

Trerotola_COMBO_R01.31

195:11 Q. Has a patient who has experienced
 195:12 complications from a Bard filter and now the question
 195:13 is whether the retrieval is difficult or already has
 195:14 been difficult, correct?
 195:15 A. Yeah.
 195:16 Q. And based upon the complication and the
 195:17 difficulty, Bard will have that doctor -- will contact
 195:18 you and put you in touch with that doctor?
 195:19 A. That's correct.
 195:20 Q. And Bard will pay you to talk to that
 195:21 doctor on how to address the complications that
 195:22 resulted from the filter?
 195:23 A. We usually have a short conversation, so
 195:24 we're talking about a pretty small payment that is
 196:1 really about doc to doc conversation about getting that
 196:2 patient better.

5:24 - 6:2

Trerotola, Scott 01-20-2017 (00:00:04)

Trerotola_COMBO_R01.69

5:24 Would you please state your name for the
 6:1 record, please.
 6:2 A. Scott Trerotola.

Plaintiff Designations = 00:02:33

Bard Designations = 00:08:43

Total Time = 00:11:16

Exhibit R

Designation Run Report

Vierling 05-11-16 Jones Trial Designations V6

Vierling, Carol 05-11-2016

Plaintiffs Designations 00:17:15

Defense Designations 00:05:42

Total Time 00:22:57



05_14_18 Combo Jones V6-Vierling 05-11-16 Jones Trial Designations V6

Page/Line	Source	ID
8:19 - 8:20	Vierling, Carol 05-11-2016 (00:00:02) 8:19 Q. Good morning, Ms. Vierling. 8:20 A. Good morning.	05_14_18 Combo Jones V6.1
9:24 - 10:7	Vierling, Carol 05-11-2016 (00:00:21) 9:24 Tell us about a thumbnail sketch on your 10:1 educational background? 10:2 A. Sure. 10:3 I have a bachelor's degree in nursing and 10:4 I also have a master's in business administration. 10:5 Q. Okay. And you also have training and 10:6 board certification in a -- in regulatory? 10:7 A. Yes. I am regulatory affairs certified.	05_14_18 Combo Jones V6.2
10:18 - 10:23	Vierling, Carol 05-11-2016 (00:00:15) 10:18 Q. And when did you go to work with 10:19 Bard? 10:20 A. In 1994. 10:21 Q. And how long were you with Bard? 10:22 A. For ten years, just short of ten years in 10:23 2002, July was my last day at Bard.	05_14_18 Combo Jones V6.3
18:22 - 19:8	Vierling, Carol 05-11-2016 (00:00:43) 18:22 Q. Okay. Specifically, the clinical 18:23 information should demonstrate that the RF, which is 18:24 the initials they are using here for Recovery filter, 19:1 has similar performance characteristics (for example, 19:2 deliverability, clot device trapping ability, freedom 19:3 from perforation, migration and fracture) as the SNF 19:4 and can safely be removed upon misplacement. 19:5 So, is this the, more or less the roadmap 19:6 that the FDA is saying what you need to follow to get 19:7 clearance for the Recovery filter? 19:8 A. It seems so, yes.	05_14_18 Combo Jones V6.4
27:15 - 27:20	Vierling, Carol 05-11-2016 (00:00:21) 27:15 So at this point, this is the 27:16 beginning of the study that we are talking about now, 27:17 the study that was submitted to the FDA as a special 27:18 510(k) submission over your signature, is that -- is 27:19 that correct? 27:20 A. Yes.	05_14_18 Combo Jones V6.7
29:3 - 29:9	Vierling, Carol 05-11-2016 (00:00:27) 29:3 Q. Okay. So as the regulatory liaison,	05_14_18 Combo Jones V6.8

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29:4 the gatekeeper, if you will, were you -- what was your
29:5 role in implementing the plan that the FDA had called
29:6 for in order to get clearance for the Recovery
29:7 device?

29:8 A. I certainly was responsible for writing
29:9 the 510(k).

31:23 - 32:3 **Vierling, Carol 05-11-2016 (00:00:09)**

05_14_18 Combo Jones V6.9

31:23 Q. the truth and accuracy
31:24 statement that we previously talked about is part
32:1 of -- is in -- is contained within this document, is
32:2 that correct?

32:3 A. Yes.

32:4 - 32:11 **Vierling, Carol 05-11-2016 (00:00:26)**

05_14_18 Combo Jones V6.10

32:4 Q. So is the effect of that you are
32:5 saying that you are verifying to the FDA that all of
32:6 the matters contained herein to the best of your
32:7 knowledge is -- are true and correct and that it
32:8 has -- contains all materials, that there are no
32:9 omissions?

32:10 A. That's what my statement on the truthful
32:11 and accuracy statement says.

32:16 - 33:7 **Vierling, Carol 05-11-2016 (00:00:55)**

05_14_18 Combo Jones V6.11

32:16 Q. Now, as the gatekeeper, you
32:17 have duties and responsibilities. What are your
32:18 duties to the FDA as the gatekeeper or as the
32:19 liaison?

32:20 A. My responsibility is to provide FDA with
32:21 information about the product, the testing, labeling,
32:22 all of the information that FDA needs in order to
32:23 determine if it's substantially equivalent to the
32:24 predicate device. And if I had remained with the
33:1 company, it would have been my responsibility to
33:2 answer any follow-up questions with FDA.

33:3 Q. Okay. Does the FDA work basically on
33:4 an honor system with the manufacturers, device
33:5 manufacturers and pharmaceutical companies in
33:6 that they rely upon the data presented to them by
33:7 the manufacturers?

33:11 - 33:11 **Vierling, Carol 05-11-2016 (00:00:02)**

05_14_18 Combo Jones V6.12

33:11 A. I would say that's true.

05_14_18 Combo Jones V6-Vierling 05-11-16 Jones Trial Designations V6

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36:17 - 36:19	Vierling, Carol 05-11-2016 (00:00:12) 36:17 Q. You also had a duty to the medical 36:18 profession to see to it that the -- you are putting a 36:19 safe and effective product on the market?	05_14_18 Combo Jones V6.13
36:23 - 36:24	Vierling, Carol 05-11-2016 (00:00:03) 36:23 A. I believe, yes, I do have that 36:24 responsibility.	05_14_18 Combo Jones V6.14
37:2 - 37:5	Vierling, Carol 05-11-2016 (00:00:19) 37:2 Q. Now, most importantly, do you also 37:3 feel as the gatekeeper in the recovery case that you 37:4 owe a duty to the ultimate user, the end user, the 37:5 person in whose body the IVC filter will be implanted?	05_14_18 Combo Jones V6.15
37:9 - 37:9	Vierling, Carol 05-11-2016 (00:00:03) 37:9 A. Yes, I do feel responsible.	05_14_18 Combo Jones V6.16
37:11 - 38:1	Vierling, Carol 05-11-2016 (00:00:39) 37:11 Q. And basically your guiding light for all 37:12 of this, for the various duties and responsibilities 37:13 that you have, would be the truth and accuracy 37:14 statement that you signed with the FDA, the same thing 37:15 applying to everybody else, is that correct? 37:16 A. Yes, although for me it goes beyond that. 37:17 It's an ethical consideration, a moral obligation to 37:18 be truthful and honest. 37:19 Q. And when you say it goes beyond that too, 37:20 you're saying -- does that apply to the duty to the 37:21 ethical and moral obligation to the end user of the 37:22 products? 37:23 A. Yes. 37:24 Q. And to the medical profession? 38:1 A. Yes.	05_14_18 Combo Jones V6.17
51:13 - 51:22	Vierling, Carol 05-11-2016 (00:00:30) 51:13 Q. So what is the proper procedure if you 51:14 cannot make a determination of a root cause analysis 51:15 when you are dealing with something such as this, in 51:16 this case a migration, what is the proper procedure? 51:17 A. You proceed with caution and watch to see 51:18 if it occurs again. At this point you don't know if 51:19 you have a problem or not because you can't determine 51:20 what caused it. 51:21 Q. And if it does occur again, then what do	05_14_18 Combo Jones V6.18

05_14_18 Combo Jones V6-Vierling 05-11-16 Jones Trial Designations V6

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51:24 - 52:12	<p>51:22 you do?</p> <p>Vierling, Carol 05-11-2016 (00:00:43)</p> <p>51:24 BY THE WITNESS:</p> <p>52:1 A. The project team would have to get</p> <p>52:2 together and talk about it. Research, quality</p> <p>52:3 assurance, all of the people involved in the team</p> <p>52:4 would have to talk about the migration, determine what</p> <p>52:5 plan of action would be taken.</p> <p>52:6 Q. And Robert Carr says that they would</p> <p>52:7 revisit the filter design. So if it occurs</p> <p>52:8 again and you don't have a root cause analysis from</p> <p>52:9 the first time, then you have to re -- revisit</p> <p>52:10 your filter design to see if there is a fundamental</p> <p>52:11 flaw in the filter itself that's causing the --</p> <p>52:12 allowing the migration?</p>	05_14_18 Combo Jones V6.19
52:14 - 52:19	<p>Vierling, Carol 05-11-2016 (00:00:15)</p> <p>52:14 BY THE WITNESS:</p> <p>52:15 A. It sounds as if they want to take a look</p> <p>52:16 at the filter design. If they don't know what the</p> <p>52:17 root cause is then they don't know that the design is</p> <p>52:18 the issue, but it sounds as though they want to</p> <p>52:19 reevaluate the design if another migration occurs.</p>	05_14_18 Combo Jones V6.20
77:8 - 77:12	<p>Vierling, Carol 05-11-2016 (00:00:36)</p> <p>77:8 Q. Okay. Now, Dr. Asch has testified that he</p> <p>77:9 indicated to Bard, the people he was dealing with at</p> <p>77:10 Bard, that the -- his study was not sufficient to</p> <p>77:11 provide a basis for the only clinical data for a</p> <p>77:12 510(k) submission.</p>	05_14_18 Combo Jones V6.21
77:15 - 77:18	<p>Vierling, Carol 05-11-2016 (00:00:05)</p> <p>77:15 A. I don't remember Dr. Asch ever telling me</p> <p>77:16 that, no.</p> <p>77:17 Q. No, no, he didn't -- he doesn't indicate</p> <p>77:18 he said it to you.</p>	05_14_18 Combo Jones V6.22
77:19 - 77:21	<p>Vierling, Carol 05-11-2016 (00:00:03)</p> <p>77:19 A. Oh, that he told it to Bard?</p> <p>77:20 Q. Yes.</p> <p>77:21 A. I don't remember.</p>	05_14_18 Combo Jones V6.23
78:2 - 78:13	<p>Vierling, Carol 05-11-2016 (00:00:27)</p> <p>78:2 Q. Do you recall Dr. Asch -- the Dr. Asch</p> <p>78:3 study was supposed to be a retrieval only study, is</p>	05_14_18 Combo Jones V6.24

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78:4 that correct, just studying whether you can put it in

78:5 and take it out safely?

78:6 A. I believe it was looking at

78:7 intraprocedural retrieval.

78:8 Q. He was just trying to establish that it

78:9 can be safely taken out --

78:10 A. Yes.

78:11 Q. -- without tearing the interior surface of

78:12 the vena cava?

78:13 A. Yes.

78:23 - 79:3 **Vierling, Carol 05-11-2016 (00:00:22)**

05_14_18 Combo Jones V6.25

78:23 Q. If -- if Dr. Asch told Robert Carr that

78:24 the data from his own clinical trial that we've been

79:1 talking about here is certainly not sufficient to

79:2 support a submission of a 510(k) for a permanent

79:3 device, should that information have come to you?

79:6 - 79:18 **Vierling, Carol 05-11-2016 (00:00:33)**

05_14_18 Combo Jones V6.26

79:6 BY THE WITNESS:

79:7 A. If that was Dr. Asch's opinion, I would

79:8 have liked to have known about it.

79:9 BY MR. NATIONS:

79:10 Q. How would it have influenced your handling

79:11 of the data for the 510(k), if at all?

79:12 A. I think we would have pulled the team

79:13 together, discussed his concerns. We may have talked

79:14 to Dr. Kaufman who was also involved in vena cava

79:15 filters to get additional medical opinion, talked to

79:16 our own scientific officer as well. I think it's

79:17 important to talk about those concerns and decide if

79:18 we should move forward.

88:9 - 88:12 **Vierling, Carol 05-11-2016 (00:00:09)**

05_14_18 Combo Jones V6.29

88:9 Q. And yet after you did the investigation,

88:10 nobody had an answer as to why it happened, did they?

88:11 A. According to the report, they could not

88:12 determine the root cause.

88:20 - 88:23 **Vierling, Carol 05-11-2016 (00:00:15)**

05_14_18 Combo Jones V6.30

88:20 Q. But how is not determining a cause an

88:21 answer? That seems to me the answer of "we looked at

88:22 it and we can't figure it out" would not be

88:23 satisfactory to the person in charge of the submittal?

05_14_18 Combo Jones V6-Vierling 05-11-16 Jones Trial Designations V6

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89:4 - 89:7	Vierling, Carol 05-11-2016 (00:00:12) 89:4 A. So if they did all due diligence to try to 89:5 figure out what the root cause was and was not -- were 89:6 not able to determine that, then I would accept that. 89:7 Again, we would watch and wait and see what happened.	05_14_18 Combo Jones V6.31
97:5 - 97:23	Vierling, Carol 05-11-2016 (00:00:52) 97:5 Q. Did you know that the -- at the time you 97:6 filed the 510(k) that the reported migration rate for 97:7 the SNF filter on the data -- the only data that Bard 97:8 had was 1,370 times greater than it was for the SNF? 97:9 A. I did not know that. 97:10 Q. Isn't that something you should have 97:11 known? 97:12 A. Failure rates are not part of the 510(k) 97:13 submission. Marketing data, what happens to the 97:14 product after it's already on the market is very 97:15 different than the data we put in the premarket 97:16 submission. 97:17 Q. And as a person just looking out for the 97:18 safety of patients in the future, that's not something 97:19 you even looked at? 97:20 A. I looked at the safety of the Recovery 97:21 filter based on the data we had and in my mind that 97:22 showed that the Recovery filter was safe. So, no, I 97:23 did not compare it to the Simon Nitinol filter.	05_14_18 Combo Jones V6.32
98:1 - 98:10	Vierling, Carol 05-11-2016 (00:00:25) 98:1 one of the reasons that you thought it was 98:2 okay to do the 510(k) submittal is that you only had 98:3 one failure in a relatively small study, right? 98:4 A. We had one failure in a small study, yes. 98:5 Q. And that's the only study Bard ever did? 98:6 A. I don't know that. 98:7 Q. While you were there? 98:8 A. While I was there, yes. 98:9 Q. Prior to the 510(k) submission? 98:10 A. As far as I know, yes.	05_14_18 Combo Jones V6.33
98:11 - 98:18	Vierling, Carol 05-11-2016 (00:00:21) 98:11 Q. And you said you didn't know if the 98:12 migration rate was a trend or an outlier. 98:13 Do you remember that?	05_14_18 Combo Jones V6.34

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98:14 A. Yes.

98:15 Q. So isn't the best way to determine whether
98:16 that migration rate was a trend or an outlier to do a
98:17 more comprehensive clinical study and answer that
98:18 question?

98:20 - 99:7

Vierling, Carol 05-11-2016 (00:00:26)

05_14_18 Combo Jones V6.35

98:20 BY THE WITNESS:

98:21 A. A more comprehensive study could have been
98:22 performed.

98:23 BY MR. BOATMAN:

98:24 Q. Well, I mean, you are sitting here with a
99:1 potentially fatal problem that's been identified in
99:2 the first 32 patients -- or 33 patients, so my
99:3 question to you is: At that time did you think to
99:4 yourself, we've got to determine whether this is a
99:5 trend or an outlier?

99:6 A. You said potentially fatal. No one died
99:7 in the clinical study.

99:12 - 99:14

Vierling, Carol 05-11-2016 (00:00:06)

05_14_18 Combo Jones V6.36

99:12 Q. the answer of whether this was a
99:13 trend or an outlier was determined when Bard put the
99:14 product on the market, wasn't it?

99:18 - 100:5

Vierling, Carol 05-11-2016 (00:00:20)

05_14_18 Combo Jones V6.37

99:18 BY THE WITNESS:

99:19 A. Whether it was a trend or an outlier was
99:20 determined as part of the clinical study, yes.

99:21 BY MR. BOATMAN:

99:22 Q. It was determined as far as the clinical
99:23 study?

99:24 A. I believe it was an N of 1, if I'm correct
100:1 in that.

100:2 Q. So, I'm sorry. I thought you didn't know
100:3 if it was a trend or an outlier. Which was it?

100:4 A. I don't know. You are right. I'm sorry.
100:5 I don't know.

100:6 - 100:9

Vierling, Carol 05-11-2016 (00:00:10)

05_14_18 Combo Jones V6.38

100:6 Q. And the choices were to do a more
100:7 comprehensive clinical study and answer that question
100:8 or put it on the market and see what happens when it
100:9 is put in patients, right?

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100:12 - 100:18	Vierling, Carol 05-11-2016 (00:00:11) 100:12 A. I don't know what the decisions were, what 100:13 the choices were. 100:14 BY MR. BOATMAN: 100:15 Q. Well, you were in charge of the decision. 100:16 Your decision was -- 100:17 A. I filed a 510(k). What happened after 100:18 that was not my responsibility.	05_14_18 Combo Jones V6:39
101:1 - 101:4	Vierling, Carol 05-11-2016 (00:00:09) 101:1 Q. So to answer the question of 101:2 whether it was a trend or an outlier, nothing further 101:3 was done, the consuming public was going to have to 101:4 answer that question, right?	05_14_18 Combo Jones V6:40
101:8 - 101:9	Vierling, Carol 05-11-2016 (00:00:02) 101:8 A. Nothing further was done in the clinical 101:9 study.	05_14_18 Combo Jones V6:41
101:11 - 101:12	Vierling, Carol 05-11-2016 (00:00:02) 101:11 Q. And you were comfortable with that? 101:12 A. Yes.	05_14_18 Combo Jones V6:42
101:13 - 101:17	Vierling, Carol 05-11-2016 (00:00:23) 101:13 Q. Does the fact that the migration didn't 101:14 happen again in Dr. Asch's small pilot study prove 101:15 anything about the design or lead to any further 101:16 explanation or clarity about the first migration? 101:17 A. I don't understand the question.	05_14_18 Combo Jones V6:43
101:18 - 102:6	Vierling, Carol 05-11-2016 (00:00:30) 101:18 Q. In other words, does the fact that this 101:19 migration occurred tell you anything about whether the 101:20 design is safe or effective or changes need to be 101:21 made? 101:22 A. I believe an investigation was made and 101:23 they determined that design changes were not needed, 101:24 otherwise we wouldn't have filed a 510(k). 102:1 Q. Well, I think they decided we don't know 102:2 what happened and if another one occurs then we'll 102:3 look at making design changes. 102:4 Isn't that what happened? 102:5 A. I believe that was stated in one of the 102:6 reports.	05_14_18 Combo Jones V6:44
106:4 - 106:7	Vierling, Carol 05-11-2016 (00:00:10)	05_14_18 Combo Jones V6:45

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106:4 - 106:14	<p>106:4 Q. There were no design changes made to the</p> <p>106:5 filter before you submitted it for approval in the</p> <p>106:6 510(k) to go to market, correct?</p> <p>106:7 A. Yes, that's correct.</p> <p>Vierling, Carol 05-11-2016 (00:00:32)</p> <p>106:8 Q. When you compare the fracture rate in the</p> <p>106:9 SNF filter to the fracture rate that you had at the</p> <p>106:10 time of the 510(k) submittal, we had a fracture rate</p> <p>106:11 1,233 times bigger in the Recovery filter than that</p> <p>106:12 which existed in the Simon Nitinol filter.</p> <p>106:13 Were you aware of that at the time you</p> <p>106:14 made the 510(k) submission?</p>	05_14_18 Combo Jones V6.46
106:17 - 106:21	<p>Vierling, Carol 05-11-2016 (00:00:05)</p> <p>106:17 BY THE WITNESS:</p> <p>106:18 A. No, I was not.</p> <p>106:19 BY MR. BOATMAN:</p> <p>106:20 Q. Is that something that should have been</p> <p>106:21 brought to your attention?</p>	05_14_18 Combo Jones V6.47
106:23 - 107:8	<p>Vierling, Carol 05-11-2016 (00:00:23)</p> <p>106:23 BY THE WITNESS:</p> <p>106:24 A. I don't believe it was relevant to the</p> <p>107:1 510(k).</p> <p>107:2 BY MR. BOATMAN:</p> <p>107:3 Q. The fact that the Simon Nitinol filter --</p> <p>107:4 I'm sorry -- that the Recovery filter is failing at a</p> <p>107:5 rate of 1,233 times greater than that and at the</p> <p>107:6 fracture rate of the SNF was not something that you</p> <p>107:7 deemed material in evaluating the safety and</p> <p>107:8 effectiveness of the Recovery filter?</p>	05_14_18 Combo Jones V6.48
107:11 - 107:15	<p>Vierling, Carol 05-11-2016 (00:00:09)</p> <p>107:11 BY THE WITNESS:</p> <p>107:12 A. I base my confidence in the 510(k) on the</p> <p>107:13 data that we had. I did not look at the complication</p> <p>107:14 rate of the Nitinol filter and I don't think it was</p> <p>107:15 relevant.</p>	05_14_18 Combo Jones V6.49
108:3 - 108:7	<p>Vierling, Carol 05-11-2016 (00:00:12)</p> <p>108:3 Q. Okay. While you were working on the</p> <p>108:4 Recovery filter project, isn't it true that you needed</p> <p>108:5 to know the failure rates of the Simon Nitinol filter</p> <p>108:6 compared to the Recovery filter?</p>	05_14_18 Combo Jones V6.50

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108:14 - 108:20	<p>108:7 A. No.</p> <p>Vierling, Carol 05-11-2016 (00:00:29)</p> <p>108:14 Q. I'm showing you what's been marked as</p> <p>108:15 Exhibit 231. It is Bates numbers BPV-17-01-00051872.</p> <p>108:16 Do you have that up in front of you?</p> <p>108:17 A. Yes.</p> <p>108:18 Q. And it's an e-mail from you to</p> <p>108:19 Dr. Kaufman, right?</p> <p>108:20 A. Yes.</p>	<p>05_14_18 Combo Jones V6.51</p> <p>2149_VIERLING.1</p> <p>2149_VIERLING.1.4</p> <p>2149_VIERLING.1.1</p> <p>2149_VIERLING.1.2</p> <p>2149_VIERLING.1.5</p>
109:17 - 110:7	<p>Vierling, Carol 05-11-2016 (00:00:39)</p> <p>109:17 Q. And if you look at this e-mail, you can</p> <p>109:18 see you are saying, "I'm attaching to Dr. Kaufman the</p> <p>109:19 latest version of the protocol with the revisions that</p> <p>109:20 Dr. Kaufman sent to me today."</p> <p>109:21 And that's -- this is you writing, right?</p> <p>109:22 A. Yes.</p> <p>109:23 Q. And you said, "The statistic" -- "the</p> <p>109:24 statistical section needs work. I need to dig through</p> <p>110:1 the files to see what the complication rate for the</p> <p>110:2 SNF was in the final report. Since we are claiming</p> <p>110:3 substantial equivalence to the SNF, that seems</p> <p>110:4 reasonable."</p> <p>110:5 Isn't that, in fact, what you wrote on</p> <p>110:6 December 13th, 2001?</p> <p>110:7 A. Yes.</p>	<p>05_14_18 Combo Jones V6.52</p> <p>2149_VIERLING.1.2</p> <p>2149_VIERLING.1.5</p>
110:8 - 110:21	<p>Vierling, Carol 05-11-2016 (00:00:39)</p> <p>110:8 Q. And doesn't that suggest to you that part</p> <p>110:9 of your analysis in determining substantial</p> <p>110:10 equivalence is, in fact, to compare the complication</p> <p>110:11 rate of the SNF to the Recovery filter?</p> <p>110:12 A. The statistical section I'm referring to</p> <p>110:13 here is part of how do we determine the sample size</p> <p>110:14 that's needed to show safety and effectiveness in this</p> <p>110:15 study. And so the complication rate of the Simon</p> <p>110:16 Nitinol filter would have been important in</p> <p>110:17 determining how many patients we needed to study using</p> <p>110:18 the Recovery filter. So I do not believe I was</p> <p>110:19 talking about the complication rate as it relates to</p> <p>110:20 the safety and effectiveness but the complication rate</p> <p>110:21 to determine sample size.</p>	<p>05_14_18 Combo Jones V6.53</p> <p>clear</p>

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111:8 - 112:4

Vierling, Carol 05-11-2016 (00:01:00)

05_14_18 Combo Jones V6.54

111:8 Q. And just as a matter of common sense when
 111:9 you are comparing a new product to the old product,
 111:10 don't you want to see how safe the new product is
 111:11 compared to the old product as far as failures?
 111:12 A. If we had that concern or if FDA had
 111:13 required that, we would have performed a head-to-head
 111:14 study comparing the Simon Nitinol filter to the
 111:15 Recovery filter. It would have been a randomized
 111:16 clinical study. That wasn't what we performed. We
 111:17 performed the study solely on the Recovery filter and
 111:18 that's all FDA required.
 111:19 Q. And, again, I'm not asking you about what
 111:20 the FDA required. I'm asking you about what you
 111:21 required as a person that's going to be the person
 111:22 primarily responsible for putting the new product on
 111:23 the market.

111:24 A. As I testified before, I had no concerns
 112:1 about the safety of this filter or the study size.

112:2 Q. But you hadn't realized that the failure
 112:3 rates of the Recovery filter were dramatically higher
 112:4 than the failure rates of the SNF?

112:8 - 112:14

Vierling, Carol 05-11-2016 (00:00:10)

05_14_18 Combo Jones V6.55

112:8 A. We had a very small sample size with the
 112:9 Recovery filter, so I don't feel we are comparing
 112:10 apples to oranges.

112:11 BY MR. BOATMAN:

112:12 Q. And isn't the answer to a small sample
 112:13 size to do a larger sample?

112:14 A. It could be.

126:24 - 127:12

Vierling, Carol 05-11-2016 (00:00:39)

05_14_18 Combo Jones V6.106

126:24 Q. Showing you Exhibit 236, this is a
 127:1 memorandum to the Recovery Filter Project Team from
 127:2 Lynne Buchanan-Kopp, CQE.

127:3 Who is she?

127:4 A. Lynne Buchanan-Kopp was a QA person at
 127:5 Bard.

127:6 Q. Okay. And it says, "The purpose of this
 127:7 memorandum is to find the phases to the Recovery
 127:8 filter."

05_14_18 Combo Jones V6-Vierling 05-11-16 Jones Trial Designations V6

Page/Line	Source	ID
	127:9 And this memo is documenting that you've 127:10 now gone to a phased approach for the 510(k) 127:11 submittal, correct? 127:12 A. Yes.	
139:9 - 139:14	Vierling, Carol 05-11-2016 (00:00:10) 139:9 Q. Bard had an obligation to do an honest and 139:10 complete root cause analysis of any failures that 139:11 occurs in its product? 139:12 A. The law requires that, yes. 139:13 Q. And it's the ethical and moral thing to 139:14 do, right?	05_14_18 Combo Jones V6.60
139:16 - 139:17	Vierling, Carol 05-11-2016 (00:00:00) 139:16 BY THE WITNESS: 139:17 A. Yes.	05_14_18 Combo Jones V6.61
141:9 - 141:13	Vierling, Carol 05-11-2016 (00:00:13) 141:9 Q. It can -- and if you don't identify the 141:10 reason for the failure and fix the failure before you 141:11 go to market, there is a risk those failures can 141:12 happen again putting hundreds of thousands of 141:13 potential patients at risk, correct?	05_14_18 Combo Jones V6.62
141:15 - 142:6	Vierling, Carol 05-11-2016 (00:00:31) 141:15 BY THE WITNESS: 141:16 A. That's a risk, yes. 141:17 BY MR. BOATMAN: 141:18 Q. And that's a consequence of not doing a 141:19 proper root cause analysis, right? 141:20 A. I don't think we established an improper 141:21 root cause analysis was performed. I think we 141:22 established that no root cause can be determined. 141:23 Q. And I understand. 141:24 And the question is: What are the 142:1 consequences of not doing a root cause analysis, of 142:2 not doing a proper one, and the reason you have to be 142:3 so careful is because you are putting tens or hundreds 142:4 of thousands of future patients at risk if you don't 142:5 do a proper root cause analysis, correct? 142:6 A. Yes.	05_14_18 Combo Jones V6.63
142:10 - 142:13	Vierling, Carol 05-11-2016 (00:00:10) 142:10 Q. For those reasons, you would agree that a 142:11 proper root cause analysis is one of the most	05_14_18 Combo Jones V6.64

Page/Line	Source	ID
142:15 - 142:16	<p>142:12 important responsibilities a company has in the</p> <p>142:13 development of a medical device?</p> <p>Vierling, Carol 05-11-2016 (00:00:01)</p> <p>142:15 BY THE WITNESS:</p>	05_14_18 Combo Jones V6.65
143:20 - 144:12	<p>142:16 A. Yes, I would agree with that.</p> <p>Vierling, Carol 05-11-2016 (00:00:36)</p> <p>143:20 Q. Because if you don't identify the reason</p> <p>143:21 it failed, you can't design a fix, right?</p> <p>143:22 A. You don't know why it failed and you are</p> <p>143:23 not able to correct any deficiency, yes.</p> <p>143:24 Q. So once you identify the reason for the</p> <p>144:1 failure, the next step is what?</p> <p>144:2 A. You determine if there are any actions</p> <p>144:3 that can be taken to correct the problem.</p> <p>144:4 Q. You fix the problem?</p> <p>144:5 A. Right.</p> <p>144:6 Q. You find out what the problem is and then</p> <p>144:7 you fix it, right?</p> <p>144:8 A. If you are able to determine why it</p> <p>144:9 failed, yes.</p> <p>144:10 Q. If it's a design issue, you change the</p> <p>144:11 design of the device, right?</p> <p>144:12 A. I would agree with that, yes.</p>	05_14_18 Combo Jones V6.66
144:19 - 144:23	<p>Vierling, Carol 05-11-2016 (00:00:11)</p> <p>144:19 Q. Okay. And then after you've figured out</p> <p>144:20 the problem, designed a fix to the problem, what's the</p> <p>144:21 next step?</p> <p>144:22 A. Then you put the fix in place and you</p> <p>144:23 monitor to see if the fix was successful.</p>	05_14_18 Combo Jones V6.67
144:24 - 145:7	<p>Vierling, Carol 05-11-2016 (00:00:14)</p> <p>144:24 Q. You do validity testing of the fix?</p> <p>145:1 A. Right.</p> <p>145:2 Q. To make sure your hypothesis of both the</p> <p>145:3 failure and the fix are correct?</p> <p>145:4 A. Yes.</p> <p>145:5 Q. And that's something any responsible</p> <p>145:6 medical device manufacturer should do when it</p> <p>145:7 encounters a failure, right?</p>	05_14_18 Combo Jones V6.68
145:9 - 145:10	<p>Vierling, Carol 05-11-2016 (00:00:01)</p> <p>145:9 BY THE WITNESS:</p>	05_14_18 Combo Jones V6.69

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186:4 - 186:16	<p>145:10 A. I agree.</p> <p>Vierling, Carol 05-11-2016 (00:00:36)</p> <p>186:4 Q. Now, the Plaintiffs counsel asked</p> <p>186:5 you some questions which implied that Bard was making</p> <p>186:6 an effort to somehow sneak out of a responsibility to</p> <p>186:7 do a clinical study with respect to the Recovery</p> <p>186:8 filter.</p> <p>186:9 What was your experience when you were at</p> <p>186:10 Bard relative to that?</p> <p>186:11 A. I didn't have any experience where I</p> <p>186:12 thought they were trying to sneak out of doing a</p> <p>186:13 clinical study. They wanted to show that the device</p> <p>186:14 was safe and effective. We believed that the Asch</p> <p>186:15 data would support that. And that's what we went</p> <p>186:16 forward with.</p>	05_14_18 Combo Jones V6.93
203:16 - 203:21	<p>Vierling, Carol 05-11-2016 (00:00:29)</p> <p>203:16 Q. Okay. If you would look at that and tell</p> <p>203:17 me what that indicates was reported to the FDA about</p> <p>203:18 number of fractures in Patient 33?</p> <p>203:19 A. This talks about the broken arm and it</p> <p>203:20 also talks about the hook they believe is embedded in</p> <p>203:21 the bony tissue.</p>	05_14_18 Combo Jones V6.102
204:8 - 204:19	<p>Vierling, Carol 05-11-2016 (00:00:29)</p> <p>204:8 Now, also with respect to the Patient 33,</p> <p>204:9 Mr. Boatman showed you a portion of the investigation</p> <p>204:10 report that talked about corrective action, correct?</p> <p>204:11 A. Yes.</p> <p>204:12 Q. And you were also asked about if an event</p> <p>204:13 happens the steps that Bard may take, could take,</p> <p>204:14 should take with respect to corrective action,</p> <p>204:15 correct?</p> <p>204:16 A. Yes.</p> <p>204:17 Q. So with respect to that corrective action,</p> <p>204:18 how would you -- how would you describe what that</p> <p>204:19 corrective action was?</p>	05_14_18 Combo Jones V6.103
205:9 - 205:14	<p>Vierling, Carol 05-11-2016 (00:00:17)</p> <p>205:9 A. So, Bard determined that the labeling</p> <p>205:10 needed to be revised to specifically address patients</p> <p>205:11 who were pregnant.</p> <p>205:12 Q. And is a labeling change another way in</p>	05_14_18 Combo Jones V6.104

05_14_18 Combo Jones V6-Vierling 05-11-16 Jones Trial Designations V6

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205:13 the world of regulatory to address an event or a
205:14 problem?

205:17 - 205:19

Vierling, Carol 05-11-2016 (00:00:12)

05_14_18 Combo Jones V6.105

205:17 A. Yes. This would let physicians who are
205:18 going to use the filter know that the suprarenal
205:19 filter placement should be used in pregnant women.

Plaintiffs Designations = 00:17:15

Defense Designations = 00:05:42

Total Time = 00:22:57

Documents Shown

2149_VIERLING

Exhibit S

Designation Run Report

Wilson_COMBO_0523_R03

Wilson, Mark 01-31-2017

Plaintiff Designations 00:03:57

Def Designations 00:19:46

Both 00:00:21

Total Time 00:24:04



Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

Page/Line	Source	ID
6:5 - 6:7	Wilson, Mark 01-31-2017 (00:00:04) 6:5 Q. Good morning, sir. 6:6 Could you please state your name. 6:7 A. Mark Wilson.	Wilson_COMBO_0523_R03.1
6:19 - 6:25	Wilson, Mark 01-31-2017 (00:00:22) 6:19 Q. Okay. When did you last work for Bard? 6:20 A. My employment dates were March 2006 through 6:21 October 2010. 6:22 Q. So that's the period of time I'm going to be 6:23 asking you questions about, your involvement at Bard. 6:24 Did you work in the sales division? 6:25 A. I did.	Wilson_COMBO_0523_R03.2
17:19 - 17:25	Wilson, Mark 01-31-2017 (00:00:17) 17:19 Q. Where did you go to college? 17:20 A. University of Southern California. 17:21 Q. What years did you go to USC? 17:22 A. It would have been 1996 to 2000. 17:23 Q. What was your degree in upon graduating from 17:24 the University of Southern California? 17:25 A. Public policy and management.	Wilson_COMBO_0523_R03.3
19:1 - 19:4	Wilson, Mark 01-31-2017 (00:00:07) 19:1 Q. Had you taken the prerequisites that you 19:2 would need to take in undergraduate school to apply 19:3 to medical school? 19:4 A. I did. Yep.	Wilson_COMBO_0523_R03.4
19:7 - 19:8	Wilson, Mark 01-31-2017 (00:00:04) 19:7 Q. Have you ever worked in patient care? 19:8 A. No.	Wilson_COMBO_0523_R03.5
19:9 - 19:18	Wilson, Mark 01-31-2017 (00:00:29) 19:9 Q. Have you ever taken any classes that dealt 19:10 with the anatomy of the human body? 19:11 A. I have. 19:12 Q. Have you taken classes that discuss the 19:13 anatomy of the inferior vena cava? 19:14 A. I have. 19:15 Q. This is something you took in undergraduate? 19:16 A. Between undergraduate, self-directed 19:17 learning, and then previous organizations where we 19:18 had anatomy courses.	Wilson_COMBO_0523_R03.6
20:5 - 20:9	Wilson, Mark 01-31-2017 (00:00:17)	Wilson_COMBO_0523_R03.7

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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20:5 Q. What's your understanding as to the primary
20:6 purpose that the inferior vena cava serves?
20:7 A. It's my understanding that that is the
20:8 largest vein in the body of which the blood is
20:9 returning to the heart.

26:12 - 26:19

Wilson, Mark 01-31-2017 (00:00:27)

Wilson_COMBO_0523_R03.8

26:12 Q. So just to make sure I'm understanding your
26:13 role when you first came on board at Bard, it was to
26:14 come in at a management level to train their sales
26:15 force.

26:16 A. That's correct.

26:17 Q. And it pertained to the BPV portfolios.

26:18 A. The Bard peripheral vascular portfolio

26:19 specifically.

28:8 - 28:11

Wilson, Mark 01-31-2017 (00:00:05)

Wilson_COMBO_0523_R03.9

28:8 Q. So after about a year of being at Bard, you
28:9 began running the training of the sales force
28:10 yourself.

28:11 A. Yeah.

31:3 - 31:6

Wilson, Mark 01-31-2017 (00:00:15)

Wilson_COMBO_0523_R03.10

31:3 Q. So can you describe for me the training Bard
31:4 gave you when you were first hired to learn how to
31:5 manage its sales force, particularly as it relates to
31:6 the IVC portfolio?

31:8 - 31:14

Wilson, Mark 01-31-2017 (00:00:32)

Wilson_COMBO_0523_R03.11

31:8 THE WITNESS: I was provided with clinical
31:9 product and disease state training in addition to a
31:10 animal lab.

31:11 BY MR. SAELTZER:

31:12 Q. Did your training cover products outside of
31:13 the IVC filter family?

31:14 A. Oh, yes. Quite extensively.

32:25 - 33:8

Wilson, Mark 01-31-2017 (00:00:25)

Wilson_COMBO_0523_R03.12

32:25 Q. What background and experience did you have
33:1 relating -- related to IVC filters before you were
33:2 hired at Bard?

33:3 A. I had no background on IVC filters, but I
33:4 did have enough background on pulmonary embolism,
33:5 thromboembolic disease, and everything around the
33:6 disease state. So, in essence, I was learning the

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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33:7 devices, not necessarily the disease state, just
 33:8 because I had a little bit of that background.

34:22 - 34:24 **Wilson, Mark 01-31-2017 (00:00:03)** Wilson_COMBO_0523_R03.13
 34:22 Q. Okay. I'm sorry. You were managing the
 34:23 training of the sales force.

34:24 A. That's correct.

42:13 - 43:1 **Wilson, Mark 01-31-2017 (00:00:37)** Wilson_COMBO_0523_R03.14
 42:13 Q. In addition to responsibility to train
 42:14 new-hires -- which is on-boarding; correct?
 42:15 A. Uh-huh.
 42:16 Q. Is that a "yes"?
 42:17 A. That's correct.
 42:18 Q. Did you also have responsibility to train
 42:19 the existing sales force on a new product when a new
 42:20 product was being launched?
 42:21 A. It was a collaborative effort between
 42:22 marketing and sales training, and we would do that
 42:23 through various regional calls. We would facilitate
 42:24 that through the regional management team, and we
 42:25 would also then facilitate workshops at the national
 43:1 sales meeting.

43:9 - 43:11 **Wilson, Mark 01-31-2017 (00:00:10)** Wilson_COMBO_0523_R03.15
 43:9 So am I correct that you did have some
 43:10 responsibility for training the existing sales force
 43:11 when a new product was launched?

43:13 - 44:4 **Wilson, Mark 01-31-2017 (00:00:49)** Wilson_COMBO_0523_R03.16
 43:13 THE WITNESS: The role that I played was to
 43:14 ensure that we were applying good adult learning
 43:15 principles. The primary facilitator for new product
 43:16 launches was going to be the marketing organization.
 43:17 I would have been able to review the materials. I
 43:18 would have been able to weigh in on how we were going
 43:19 to design workshops.
 43:20 I may have facilitated a particular session
 43:21 because we typically would break the sales force out
 43:22 into groups. But we -- I would also facilitate
 43:23 training the trainers if we had multiple product
 43:24 managers that reported in to our marketing directors
 43:25 that were responsible for training. So I was also
 44:1 helping with their professional development, but my

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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54:4 - 55:7

44:2 role was specifically around assuring that we were
44:3 applying good adult learning principles and -- and
44:4 facilitating good training for the sales force.

Wilson, Mark 01-31-2017 (00:01:42)

Wilson_COMBO_0523_R03.17

54:4 Q. As part of performing your job duties at
54:5 Bard, would you receive any regular reports of
54:6 complication rates for filter -- IVC filters?

54:7 A. No.

54:8 Q. As part of performing your job duties at
54:9 Bard, would you have access to the DFMEAs?

54:10 A. No.

54:11 Q. Have you ever, while at Bard, looked at an
54:12 DFMEA for any IVC filter?

54:13 A. I did not.

54:14 Q. Do you know what a DFMEA is?

54:15 A. I recall the term from my time at Bard but
54:16 don't remember what the acronym stands for.

54:17 Q. Do you have any understanding as to what
54:18 information is within the DFMEA?

54:19 A. I don't know all the scope of what is
54:20 entailed.

54:21 Q. Did anybody at Bard ever train you on what
54:22 information is in there?

54:23 A. I don't believe I was trained on that
54:24 information.

54:25 Q. Were you ever given any training by Bard as
55:1 to their risk evaluation system?

55:2 A. I don't recall ever going through any type
55:3 of training related to risk analysis.

55:4 Q. Do you ever recall receiving any type of
55:5 regular reports of filter complications while you
55:6 were working at Bard?

55:7 A. I don't recall getting any reports.

60:25 - 61:24

Wilson, Mark 01-31-2017 (00:01:34)

Wilson_COMBO_0523_R03.18

60:25 Q. Would you regular -- regularly receive any
61:1 type of information on how a Bard IVC filter was
61:2 performing in the field?

61:3 A. I did not receive regular updates on product
61:4 performance. It wasn't in the scope for my role.

61:5 Q. So let me then ask you some questions about

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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61:6 the sales representatives and how they were trained

61:7 and how they were trained to do their job.

61:8 That fell within your responsibility; true?

61:9 A. Yes.

61:10 Q. Were the sales representatives trained to

61:11 interact directly with customers?

61:12 A. Our sales reps were trained on engaging

61:13 customers. They were also trained on clinical

61:14 product and sales training.

61:15 Q. Would the customers for an IVC filter be

61:16 doctors?

61:17 A. Yes.

61:18 Q. They would include doctors?

61:19 A. They would include doctors, yes. It could

61:20 be mid-level practitioners, as well. You know,

61:21 there's techs in -- in these -- in these facilities,

61:22 which would also be customers. They just wouldn't be

61:23 necessarily the clinicians who were implanting the

61:24 IVC filters.

62:9 - 63:2

Wilson, Mark 01-31-2017 (00:01:13)

Wilson_COMBO_0523_R03.19

62:9 Q. Were the sales force or sales reps trained

62:10 that they were the face of the company to the

62:11 doctors?

62:12 A. The sales force understood that they were

62:13 representing Bard as a territory manager in that

62:14 particular locality.

62:15 Q. Did Bard use the sales representatives as

62:16 one method to communicate information about a product

62:17 to the doctors?

62:18 A. Bard would use the sales reps as one of many

62:19 ways to communicate about Bard products to healthcare

62:20 practitioners.

62:21 Q. Did Bard train the sales reps that it was

62:22 important that they only convey accurate information

62:23 regarding IVC filter performance?

62:24 A. Bard trained the sales force to ensure that

62:25 they were communicating based on the approved claims

63:1 that were provided to us by marketing and what was in

63:2 the instructions for use.

63:3 - 63:7

Wilson, Mark 01-31-2017 (00:00:13)

Wilson_COMBO_0523_R03.20

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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63:3 Q. Were the sales force trained on why that's
63:4 important, that they should stick to what's been
63:5 approved comments regarding product performance?
63:6 A. Yes. We provided context as to why that was
63:7 critical.

63:8 - 63:8 **Wilson, Mark 01-31-2017 (00:00:01)**

Wilson_COMBO_0523_R03.21

63:8 Q. What context did you provide them?

63:10 - 63:16 **Wilson, Mark 01-31-2017 (00:00:21)**

Wilson_COMBO_0523_R03.22

63:10 THE WITNESS: There are strict regulations
63:11 via the regulatory agencies as to what is considered
63:12 to be on-label and off-label promotion, and we
63:13 provided context as to what the potential
63:14 consequences are. So the sales reps were very well
63:15 trained on what was acceptable behavior and what was
63:16 not.

64:16 - 64:25 **Wilson, Mark 01-31-2017 (00:00:34)**

Wilson_COMBO_0523_R03.23

64:16 Q. And the sales force is trained that
64:17 it's important they do not make statements regarding
64:18 product performance that haven't gone through Bard's
64:19 approval process; correct?
64:20 A. Anything related to Bard IVC filters would
64:21 have gone through our label review process. So the
64:22 sales force would not be providing doctors with
64:23 performance data that wouldn't be consistent with our
64:24 instructions for use or anything that has been
64:25 approved through our label review process.

65:2 - 65:6 **Wilson, Mark 01-31-2017 (00:00:17)**

Wilson_COMBO_0523_R03.24

65:2 So the sales force would be trained to limit
65:3 their comments regarding Bard IVC filter performance
65:4 to those statements that had gone through the Bard
65:5 approval process.

65:6 A. That's correct.

67:4 - 68:3 **Wilson, Mark 01-31-2017 (00:01:09)**

Wilson_COMBO_0523_R03.25

67:4 Q. So the first category there was approved
67:5 marketing materials. Could that include a product
67:6 brochure?
67:7 A. It would include product brochures, yeah.
67:8 Q. Can you give me an example of other type of
67:9 materials it might include?
67:10 A. It might include, like, a leave-behind that

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67:11 we would leave for the physician to reference, with
 67:12 sizing -- you know, sizing and -- and stuff that
 67:13 would come out of the instructions for use.
 67:14 There also might be -- there might be
 67:15 materials for procurement or whoever was managing the
 67:16 inventory for ordering materials and things of that
 67:17 nature. So it was all approved materials that we
 67:18 typically would provide the sales reps for launch and
 67:19 then, you know, continuous; they could order these
 67:20 materials when they would run out.
 67:21 Q. You also mentioned approved training
 67:22 manuals. Am I correct that those training manuals
 67:23 would be given to the sales force but were not to be
 67:24 distributed to the doctors?
 67:25 A. The -- the sales training manuals were all
 68:1 for internal use only, and we were very -- very
 68:2 particular about marketing materials that were for
 68:3 internal use only.

70:18 - 71:15

Wilson, Mark 01-31-2017 (00:01:28)

Wilson_COMBO_0523_R03.26

70:18 Q. As head of training for Bard's IVC sales
 70:19 force, was it your understanding that doctors would
 70:20 rely upon their sales representative to provide them
 70:21 accurate information regarding the risk associated
 70:22 with IVC filters?
 70:23 A. It's my understanding and personal belief
 70:24 that the sales rep is only one small component of how
 70:25 a physician should be acquiring information. They
 71:1 should also be leveraging their own clinical
 71:2 experience, their own education, as well as their
 71:3 peers, as well as clinical data to support the use
 71:4 and decision-making in clinical practice.
 71:5 Q. But was it your understanding that
 71:6 physicians would use their sales rep- --
 71:7 representative as one source of information to learn
 71:8 about the risk associated with the product?
 71:9 A. They would use the Bard sales force as one
 71:10 source of many, a multitude of sources, to make a
 71:11 clinical decision.
 71:12 Q. Do you have any criticisms of a physician
 71:13 who used a product manufacturer as an important

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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71:17 - 72:2	<p>71:14 source of information about the risk associated with 71:15 that product?</p> <p>Wilson, Mark 01-31-2017 (00:00:37)</p> <p>71:17 THE WITNESS: I'm not a medical 71:18 professional, so I don't feel I'm qualified to answer 71:19 that question, but it is my personal belief that a 71:20 physician should use all of their resources in the 71:21 armamentarium at their disposal to make good clinical 71:22 decisions. 71:23 BY MR. SAELTZER: 71:24 Q. Is one of those information from the product 71:25 manufacturer? 72:1 A. I would say that would be included in all of 72:2 the resources available to them.</p>	Wilson_COMBO_0523_R03.27
72:23 - 73:10	<p>Wilson, Mark 01-31-2017 (00:00:55)</p> <p>72:23 Q. Were Bard sales representatives given 72:24 material regarding IVC filters to provide to doctors 72:25 that con- -- contained comparisons of how Bard 73:1 IVC filters' performance compared to other 73:2 IVC filters? 73:3 A. I don't recall a particular piece of 73:4 marketing collateral that made a competitive 73:5 comparison. I can't recall. It's been, again, 73:6 quite some time. But I know that Bard's stance would 73:7 be that, unless a randomized controlled trial 73:8 comparing them was done, we wouldn't be making a 73:9 competitive comparison like that in -- in writing. 73:10 And that's consistent with any medical manufacturer.</p>	Wilson_COMBO_0523_R03.28
73:16 - 73:19	<p>Wilson, Mark 01-31-2017 (00:00:14)</p> <p>73:16 How do you know that Bard wouldn't make a 73:17 comparison like we've discussed between its product 73:18 and a competitor's product without a randomized 73:19 controlled study to back it up?</p>	Wilson_COMBO_0523_R03.29
73:21 - 73:25	<p>Wilson, Mark 01-31-2017 (00:00:14)</p> <p>73:21 THE WITNESS: When I joined the 73:22 organization, I was trained that that would be -- 73:23 that would not be consistent with what a medical 73:24 manufacturer and, specifically, what Bard would do 73:25 without a randomized controlled trial.</p>	Wilson_COMBO_0523_R03.30
79:11 - 79:12	<p>Wilson, Mark 01-31-2017 (00:00:05)</p>	Wilson_COMBO_0523_R03.31

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

Page/Line	Source	ID
79:14 - 79:18	<p>79:11 Q. Were representatives informed they would be</p> <p>79:12 expected to sell a certain number of product?</p> <p>Wilson, Mark 01-31-2017 (00:00:16)</p> <p>79:14 THE WITNESS: They were given their -- what</p> <p>79:15 we would call their baseline, and then there would be</p> <p>79:16 a quota that was provided to them, and it would be</p> <p>79:17 consistent with every manufacturer.</p>	Wilson_COMBO_0523_R03.32
79:19 - 79:22	<p>79:18 BY MR. SAELTZER:</p> <p>Wilson, Mark 01-31-2017 (00:00:12)</p> <p>79:19 Q. The baseline or quota would be a certain</p> <p>79:20 number of units to sell over a given time period.</p>	Wilson_COMBO_0523_R03.33
79:23 - 79:25	<p>79:21 A. They were given a dollar amount as well as</p> <p>79:22 that correlating unit amount, yeah.</p> <p>Wilson, Mark 01-31-2017 (00:00:06)</p>	Wilson_COMBO_0523_R03.34
80:1 - 80:9	<p>79:23 Q. Okay. So it would be probably expressed in</p> <p>79:24 terms of a dollar amount over a given period of time.</p> <p>79:25 A. Dollars and units.</p> <p>Wilson, Mark 01-31-2017 (00:00:28)</p>	Wilson_COMBO_0523_R03.35
91:14 - 91:17	<p>80:1 Q. Were they trained on what they would</p> <p>80:2 be expected or could expect to need to do to achieve</p> <p>80:3 those goals?</p> <p>80:4 A. The district managers would probably run</p> <p>80:5 scenarios for them so they could understand, because</p> <p>80:6 it was some -- during my tenure, they were -- their</p> <p>80:7 variable compensation was done in buckets. So there</p> <p>80:8 was never any one emphasis on those buckets, or</p> <p>80:9 overemphasis, if you will.</p> <p>Wilson, Mark 01-31-2017 (00:00:24)</p>	Wilson_COMBO_0523_R03.36
91:19 - 91:24	<p>91:14 Q. Was it your understanding that Bard</p> <p>91:15 territory managers were also having to spend time</p> <p>91:16 defending the IVC filter portfolio against questions</p> <p>91:17 regarding complication and complication rates?</p> <p>Wilson, Mark 01-31-2017 (00:00:19)</p>	Wilson_COMBO_0523_R03.37
92:10 - 92:16	<p>91:19 THE WITNESS: I don't believe that it had</p> <p>91:20 anything to do with Bard filters in particular, but</p> <p>91:21 I -- I do believe it was very difficult in a</p> <p>91:22 competitive market to compete with -- with Cook and</p> <p>91:23 Cordis, two viable competitors with educated and</p> <p>91:24 well-trained reps, just like Bard.</p> <p>Wilson, Mark 01-31-2017 (00:00:30)</p>	Wilson_COMBO_0523_R03.39

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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92:10 Q. Have you ever undertaken any investigation
 92:11 to verify the statement you just made?
 92:12 A. I'm not qualified to make that assessment,
 92:13 but there are several employees within BPV who would
 92:14 be qualified. And I've been trained on that -- that
 92:15 notion, that complication rates for all filters are
 92:16 very similar.

93:5 - 93:8

Wilson, Mark 01-31-2017 (00:00:11)

Wilson_COMBO_0523_R03.40

93:5 Q. Well, one of the questions that sales
 93:6 representatives were trained to field from doctors
 93:7 was: How does your product stack up against the
 93:8 competitors' products? True?

93:10 - 93:22

Wilson, Mark 01-31-2017 (00:00:53)

Wilson_COMBO_0523_R03.41

93:10 THE WITNESS: We would specifically train
 93:11 the sales reps on the approved marketing claims and
 93:12 instructions for use for Bard filters. So we didn't
 93:13 necessarily train them on how to make a comparison,
 93:14 because we didn't have data that would allow us to be
 93:15 able to train them to make a competitive comparison
 93:16 between the two, other than what was public
 93:17 information from a Cook or from a Cordis.

93:18 BY MR. SAELTZER:

93:19 Q. Isn't it true that one of the questions that
 93:20 sales representatives were trained to field from
 93:21 doctors was how Bard IVC filters compared in
 93:22 performance to other IVC filters?

93:24 - 93:24

Wilson, Mark 01-31-2017 (00:00:02)

Wilson_COMBO_0523_R03.42

93:24 THE WITNESS: That's not correct.

94:1 - 94:4

Wilson, Mark 01-31-2017 (00:00:10)

Wilson_COMBO_0523_R03.43

94:1 BY MR. SAELTZER:

94:2 Q. Isn't that one of the questions that Bard
 94:3 expected to be asked of their sales representatives
 94:4 by doctors?

94:6 - 94:9

Wilson, Mark 01-31-2017 (00:00:10)

Wilson_COMBO_0523_R03.44

94:6 THE WITNESS: We would anticipate that
 94:7 question would come up, but what the reps were
 94:8 trained to do was to inform the physicians that a
 94:9 comparison between these two filters cannot be made.

95:11 - 95:16

Wilson, Mark 01-31-2017 (00:00:25)

Wilson_COMBO_0523_R03.47

95:11 Q. One of the topics you expected sales

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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97:15 - 97:25	<p>95:12 representatives to be able to manage is the</p> <p>95:13 expectations of doctors regarding filter</p> <p>95:14 complications.</p> <p>95:15 A. Yes. New -- new physicians oftentimes would</p> <p>95:16 inquire about complications related to filters.</p> <p>Wilson, Mark 01-31-2017 (00:00:38)</p> <p>97:15 Q. Then, if you look at the first sentence,</p> <p>97:16 you're telling Mr. Baird that one element learned</p> <p>97:17 from his research is that physicians don't want a</p> <p>97:18 filter to move; is that correct?</p> <p>97:19 A. I think that looks like something that I may</p> <p>97:20 have learned and I summarized in the e-mail.</p> <p>97:21 Q. And what you learned was that doctors do not</p> <p>97:22 want filters to migrate after they've been implanted;</p> <p>97:23 true?</p> <p>97:24 A. Yes. "Move" would be synonymous with</p> <p>97:25 "migration."</p>	Wilson_COMBO_0523_R03.48
107:19 - 107:23	<p>Wilson, Mark 01-31-2017 (00:00:20)</p> <p>107:19 Q. Certainly you would never instruct the sales</p> <p>107:20 force to pass along a sales brochure saying the G2</p> <p>107:21 had increased migration resistance if Bard's own</p> <p>107:22 prediction was that the G2 would migrate more</p> <p>107:23 frequently than the SNF; true?</p>	Wilson_COMBO_0523_R03.49
107:25 - 108:3	<p>Wilson, Mark 01-31-2017 (00:00:09)</p> <p>107:25 THE WITNESS: That would be outside the</p> <p>108:1 scope of my decision-making. What we would train the</p> <p>108:2 sales force on is what was contained in the sales</p> <p>108:3 brochure.</p>	Wilson_COMBO_0523_R03.50
110:18 - 110:20	<p>Wilson, Mark 01-31-2017 (00:00:10)</p> <p>110:18 Q. As the head of training of sales at Bard,</p> <p>110:19 that's the type of information you would have liked</p> <p>110:20 to have known; true?</p>	Wilson_COMBO_0523_R03.57
110:22 - 111:20	<p>Wilson, Mark 01-31-2017 (00:01:17)</p> <p>110:22 THE WITNESS: I don't have any expectation</p> <p>110:23 on anyone to share data. That wouldn't be</p> <p>110:24 necessarily something we would share with the broader</p> <p>110:25 sales force.</p> <p>111:1 So, at some point, if somebody in the</p> <p>111:2 regulatory, kind of, medical services and executive</p> <p>111:3 team made a decision not to share that information</p>	Wilson_COMBO_0523_R03.58

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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111:4 specifically with me, I -- I trust that there --
 111:5 there was not a reason for me to have that
 111:6 information to share with the sales force, because we
 111:7 typically would train the sales force on objection
 111:8 handling, what's -- happens to be in the brochure,
 111:9 the FAQs that marketing provides.
 111:10 So I trust in the -- the leadership and
 111:11 appropriate people within the Bard organization to
 111:12 share with me what I needed to know in order to
 111:13 support the sales organization.
 111:14 BY MR. SAELTZER:
 111:15 Q. Would you have felt comfortable training
 111:16 sales representatives to hand doctors this G2 sales
 111:17 brochure stating that the G2 had enhanced fracture
 111:18 resistance if Bard's own internal risk estimate was
 111:19 that the G2 was ten times more likely to fracture and
 111:20 cause life-threatening injury than the SNF?

111:22 - 112:3

Wilson, Mark 01-31-2017 (00:00:25)

Wilson_COMBO_0523_R03.59

111:22 THE WITNESS: I had no quarrels with putting
 111:23 this into the hands of the sales force, because this
 111:24 had obviously been vetted through our label review
 111:25 process, and I trusted in our process. We had some
 112:1 very educated and well-informed reviewers from
 112:2 regulatory, legal, and medical reviewing materials
 112:3 before we handed them to the sales force.

112:4 - 112:16

Wilson, Mark 01-31-2017 (00:00:50)

Wilson_COMBO_0523_R03.60

112:4 BY MR. SAELTZER:

112:5 Q. And I understand you trusted in the process
 112:6 to give you accurate information, but what I'm asking
 112:7 you is: If you learned what I'm telling you, that,
 112:8 at the time this sales brochure was created for the
 112:9 launch of the G2, Bard had done a risk analysis that
 112:10 estimated the G2 would fracture and cause
 112:11 life-threatening -- potentially life-threatening
 112:12 injuries at a rate ten times that of the SNF and that
 112:13 the system didn't work; it broke down in that
 112:14 regards -- if you knew that, you wouldn't feel
 112:15 comfortable training sales representatives to
 112:16 distribute this brochure; true?

112:18 - 112:21

Wilson, Mark 01-31-2017 (00:00:09)

Wilson_COMBO_0523_R03.61

Wilson_COMBO_0523_R03-Wilson_COMBO_0523_R03

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112:18 THE WITNESS: I would ask questions about
112:19 the -- the data, and it would flag me to have a
112:20 conversation with someone before distributing the
112:21 brochure.

Plaintiff Designations = 00:03:57

Def Designations = 00:19:46

Both = 00:00:21

Total Time = 00:24:04

Plaintiff Designations

Def Designations

Both

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Exhibit T

Designation Run Report

Wong 10-18-16 Jones Trial Designations V9

Wong, Natalie 10-18-2016

Plaintiffs Designations 00:24:46

Defense Designations 00:14:58

Pliaintiffs and Defense Designations 00:03:05

Total Time 00:42:49



05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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8:10 - 8:12	Wong, Natalie 10-18-2016 (00:00:03) 8:10 Q. Hey, good morning, ma'am. Will you please 8:11 tell us your name? 8:12 A. Natalie Wong.	05_21_18 Combo Jones V9.1
10:3 - 10:6	Wong, Natalie 10-18-2016 (00:00:10) 10:3 Q. What is your educational background? Can 10:4 you give us just a quick snapshot? 10:5 A. Sure. I have a bachelor's of engineering 10:6 from ASU. And I have an MBA from ASU.	05_21_18 Combo Jones V9.102
10:7 - 10:16	Wong, Natalie 10-18-2016 (00:00:29) 10:7 Q. Any particular kind of engineering? 10:8 A. Industrial. 10:9 Q. And what does industrial engineering 10:10 entail? 10:11 A. The first two years is the same as any 10:12 other engineering curriculum, it's the basic statics, 10:13 dynamics, statistics, Engineering 101. And then the 10:14 upper-level classes are more towards quality, 10:15 production, molding, simulation, those type of 10:16 courses.	05_21_18 Combo Jones V9.2
13:6 - 13:8	Wong, Natalie 10-18-2016 (00:00:03) 13:6 Q. Is calculating statistical significance 13:7 something you know how to do? 13:8 A. Yes.	05_21_18 Combo Jones V9.3
13:16 - 13:21	Wong, Natalie 10-18-2016 (00:00:09) 13:16 Q. When you started at Bard, you were 13:17 doing statist -- statistical calculations. Fair? 13:18 A. Yes. 13:19 Q. Okay. And some of those calculations were 13:20 calculating statistical significance? 13:21 A. Yes.	05_21_18 Combo Jones V9.4
17:10 - 17:15	Wong, Natalie 10-18-2016 (00:00:12) 17:10 You're currently employed with Bard 17:11 Peripheral Vascular; is that correct? 17:12 A. Yes. 17:13 Q. And what is your current position? 17:14 A. I'm quality engineering manager for new 17:15 product development under biopsy products.	05_21_18 Combo Jones V9.5
20:4 - 20:12	Wong, Natalie 10-18-2016 (00:00:30) 20:4 Q. what is a DFMEA?	05_21_18 Combo Jones V9.6

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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20:5 A. It stands for design, failure, modes,
 20:6 effects and analysis and we go through an entire
 20:7 procedure and help identify what are the risks that
 20:8 can occur. The severity of the risk to the patient
 20:9 or physician? What causes occurred. What type of
 20:10 things could have occur that would result in a
 20:11 certain failure mode. What controls we have in place
 20:12 to mitigate those risks.

20:13 - 20:16

Wong, Natalie 10-18-2016 (00:00:08)

05_21_18 Combo Jones V9.7

20:13 Q. So what is the overall purpose of a -- of a
 20:14 what's Bard really use that for?

20:15 A. To identify failure modes and risks to the
 20:16 patient.

20:17 - 20:21

Wong, Natalie 10-18-2016 (00:00:13)

05_21_18 Combo Jones V9.8

20:17 Q. Okay. And what happens if a -- if a risk
 20:18 to the patient or failure mode is identified? What
 20:19 happens from there?

20:20 A. We do -- we identify the appropriate
 20:21 testing to mitigate that risk.

22:23 - 23:21

Wong, Natalie 10-18-2016 (00:01:01)

05_21_18 Combo Jones V9.9

22:23 Q. And if a new failure mode is identified
 22:24 and -- and you're in the process of updating the
 22:25 DFMEA, what is done with regard to that product
 23:1 that's already being sold?

23:2 A. That would need to go through the
 23:3 investigation process.

23:4 Q. Well, what if -- what if a product is
 23:5 already being sold and the updated DFMEA shows that
 23:6 it's in a Quad 3, for example? What -- what would
 23:7 happen from that point?

23:8 A. We would need to evaluate it. We would
 23:9 need to investigate it, and understand what it means.

23:10 Q. Okay. What is done during that evaluation
 23:11 to -- to warn physicians and patients about the fact
 23:12 that -- that this new failure mode has been
 23:13 identified, and that there's additional testing being
 23:14 done?

23:15 A. I think, first off, we need to understand
 23:16 what the failure mode is. We need to investigate it.
 23:17 We need to, as part of the investigation, we would

05_21_18 Combo Jones V9-Wong 10-18-2016 Jones Trial Designations V9

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23:18	probably request an HHE, a Health Hazard Evaluation.	
23:19	And all those inputs coming together into, you know,	
23:20	what we call our CAPA system right now. And that	
23:21	would go through management approval.	
23:25 - 24:9	Wong, Natalie 10-18-2016 (00:00:20)	05_21_18 Combo Jones V9.124
23:25	Q. What is	
24:1	done to let the physicians and patients know that	
24:2	there is this new failure mode that warrants further	
24:3	investigation by the -- by the company? What's --	
24:4	what's done to let them know about that while that's	
24:5	going on?	
24:6	A. We don't know what it is yet. We don't	
24:7	know what this new failure mode is. We need to do a	
24:8	thorough investigation to understand what it is	
24:9	before we communicate anything.	
26:24 - 26:25	Wong, Natalie 10-18-2016 (00:00:04)	05_21_18 Combo Jones V9.125
26:24	Q. Are the results of a DFMEA analysis	
26:25	important?	
27:1 - 27:1	Wong, Natalie 10-18-2016 (00:00:01)	05_21_18 Combo Jones V9.126
27:1	A. Yes. Absolutely.	
27:2 - 27:6	Wong, Natalie 10-18-2016 (00:00:12)	05_21_18 Combo Jones V9.127
27:2	Q. Why?	
27:3	A. Because you identified the severity of the	
27:4	failure modes. You know, you -- it identifies the	
27:5	failure modes that could potentially occur in the	
27:6	device before you launch.	
27:7 - 27:11	Wong, Natalie 10-18-2016 (00:00:12)	05_21_18 Combo Jones V9.128
27:7	Q. And if it ends up in, for example, a Quad 3	
27:8	or a Quad 4, what does that mean?	
27:9	A. It means that it's a high -- it's an	
27:10	alarming -- it's a high issue that we need to look at	
27:11	more deeply.	
27:12 - 27:15	Wong, Natalie 10-18-2016 (00:00:09)	05_21_18 Combo Jones V9.129
27:12	Q. Okay.	
27:13	A. You know, and do we have the controls to	
27:14	mitigate that risk? Can we reduce that risk from a	
27:15	Quad 3 to a Quad 2?	
27:16 - 27:25	Wong, Natalie 10-18-2016 (00:00:23)	05_21_18 Combo Jones V9.130
27:16	Q. And if you've got -- if you've got	
27:17	something that ends up in a Quad 3 or Quad 4, that's	

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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27:18 something that Bard needs to take action on. Right?

27:19 A. On a team level, yes, before we launch.

27:20 Q. Or if its something that's -- that's

27:21 already been launched, and it's a new failure mode,

27:22 same deal, right, something they need to take action

27:23 on?

27:24 A. They need to evaluate and determine what

27:25 the action would be, yes.

28:9 - 28:12 **Wong, Natalie 10-18-2016 (00:00:05)**

05_21_18 Combo Jones V9.16

28:9 Q. So since you started back in

28:10 February of 2004 at Bard, you've been involved in

28:11 DFMEA analysis?

28:12 A. Yes.

28:15 - 28:20 **Wong, Natalie 10-18-2016 (00:00:19)**

05_21_18 Combo Jones V9.16

28:15 as part of the DFMEA

28:16 analysis, is a root cause analysis performed for --

28:17 for various failure modes?

28:18 A. It's kind of built in, in a way, because

28:19 you identify the causes of failure for a certain

28:20 failure mode within the DFMEA.

29:17 - 29:25 **Wong, Natalie 10-18-2016 (00:00:22)**

05_21_18 Combo Jones V9.16

29:17 Q. Okay. And what do you -- what do you mean

29:18 when you say "failure mode," just so the jury

29:19 understands?

29:20 A. So something that happens, you know, if a

29:21 product -- you know, if something didn't work

29:22 correctly, as the physician intended.

29:23 Q. Okay. Or as the manufacturer intended.

29:24 Right?

29:25 A. Or the manufacturer intended, yes.

32:13 - 32:16 **Wong, Natalie 10-18-2016 (00:00:07)**

05_21_18 Combo Jones V9.17

32:13 Q. why does Bard do root cause

32:14 analysis, I mean, what's their -- why do they do

32:15 them?

32:16 A. To prevent failure modes from occurring.

32:17 - 32:19 **Wong, Natalie 10-18-2016 (00:00:05)**

05_21_18 Combo Jones V9.18

32:17 Q. And is that something that's important to

32:18 do?

32:19 A. Yes, absolutely.

32:20 - 32:22 **Wong, Natalie 10-18-2016 (00:00:04)**

05_21_18 Combo Jones V9.18

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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32:20 Q. why is it important?

32:21 A. Because we don't want complaints. We don't

32:22 want patient injury.

32:23 - 33:1

Wong, Natalie 10-18-2016 (00:00:06)

05_21_18 Combo Jones V9 20

32:23 Q. It's important to understand the root cause

32:24 of failure modes to prevent injury to patients.

32:25 Fair?

33:1 A. Yes.

33:11 - 33:16

Wong, Natalie 10-18-2016 (00:00:11)

05_21_18 Combo Jones V9 21

33:11 Q. As of the time you left filters in -- in

33:12 2012, has Bard figured out the root cause of filter

33:13 fracture?

33:14 A. No, not that I know of.

33:15 Q. How about filter migration?

33:16 A. No, not that I know of.

34:1 - 34:6

Wong, Natalie 10-18-2016 (00:00:15)

05_21_18 Combo Jones V9 22

34:1 Q. Bard continues to sell, despite not having

34:2 identified a root cause of -- of the failures of --

34:3 of its failure modes, its IVC filters for placement

34:4 in veins in patients -- in a vein that leads directly

34:5 to the heart and lungs?

34:6 A. Yes.

34:20 - 34:24

Wong, Natalie 10-18-2016 (00:00:15)

05_21_18 Combo Jones V9 23

34:20 Q. Do you think that the fact that Bard has

34:21 not now, in 12 years of selling its filters, been

34:22 able to identify the root cause of the failure modes

34:23 associated with those filters, is something a

34:24 physician would want to know?

35:6 - 35:12

Wong, Natalie 10-18-2016 (00:00:14)

05_21_18 Combo Jones V9 24

35:6 Yeah, I think physicians should know, and I

35:7 think we do communicate through the IFU.

35:8 BY MR. DEGREEFF:

35:9 Q. So you believe that in the IFU it states

35:10 that Bard has failed to identify the root cause of

35:11 the failure modes?

35:12 A. Sorry, no, not that part.

38:21 - 38:22

Wong, Natalie 10-18-2016 (00:00:07)

05_21_18 Combo Jones V9 25

38:21 Q. So prior to 2012, you were a quality

38:22 engineering manager at BPV; is that correct?

38:24 - 38:24

Wong, Natalie 10-18-2016 (00:00:00)

05_21_18 Combo Jones V9 26

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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39:15 - 39:17	38:24 Yes. Wong, Natalie 10-18-2016 (00:00:03) 39:15 were you tracking and trending complaints and 39:16 adverse events? 39:17 A. Yes.	05_21_18 Combo Jones V9.27
41:24 - 42:1	Wong, Natalie 10-18-2016 (00:00:10) 41:24 What adverse event data did you consider in 41:25 the tracking and trending? 42:1 A. We cons -- we considered all data.	05_21_18 Combo Jones V9.28
42:5 - 42:7	Wong, Natalie 10-18-2016 (00:00:04) 42:5 Q. Where did you get the adverse 42:6 event data from? 42:7 A. The complaint system.	05_21_18 Combo Jones V9.29
42:12 - 42:18	Wong, Natalie 10-18-2016 (00:00:24) 42:12 Q. And would it also include MAUDE data? 42:13 A. It -- so the complaints were reported to us 42:14 and we entered them into TrackWise, which is our 42:15 complaint-handling system. And in the system we 42:16 would identify whether or not it was an adverse 42:17 event. If it was an adverse event, then we reported 42:18 it to the FDA, which gets rolled into the MAUDE.	05_21_18 Combo Jones V9.30
43:14 - 43:18	Wong, Natalie 10-18-2016 (00:00:11) 43:14 Q. And why is it important to --to 43:15 track and trend the complaint data? 43:16 A. To understand if something is going on 43:17 that's unusual, so we can mitigate those type of 43:18 complaints.	05_21_18 Combo Jones V9.31
43:18 - 44:1	Wong, Natalie 10-18-2016 (00:00:19) 43:18 What if all of a sudden we got a spike 43:19 in a certain type of complaint for a certain failure 43:20 mode, we would want to go and investigate that. 43:21 Q. And why is it important to investigate 43:22 failure modes? 43:23 A. So we -- so we prevent future occurrence of 43:24 these complaints. 43:25 Q. And is that for -- for patient safety? 44:1 A. For patient safety, yes.	05_21_18 Combo Jones V9.32
49:1 - 49:5	Wong, Natalie 10-18-2016 (00:00:11) 49:1 When you were working on IVC filters, was 49:2 there ever a literature review performed to see	05_21_18 Combo Jones V9.33

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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49:3 what -- what adverse events were -- were referenced
 49:4 in those -- in that literature?
 49:5 A. When I was on the project team, yes.

58:5 - 58:19 **Wong, Natalie 10-18-2016 (00:00:39)**

05_21_18 Combo Jones V9.35

58:5 Q. Bard often looks at the statistical
 58:6 significance of an -- an increased risk. Correct?
 58:7 A. That's one of the ways that we look at it.
 58:8 Q. It's one of the things they look at?
 58:9 A. It is one of the things they look at, but
 58:10 they look at other things as well.
 58:11 Q. They also look at the -- at the -- for
 58:12 example, the rate of adverse events with their filter
 58:13 versus competitor filters. Fair?
 58:14 A. Yes.
 58:15 Q. And is the rate an important thing for them
 58:16 to look at?
 58:17 A. It's hard to look at it with a competitor
 58:18 filter, because most of the time we do not have
 58:19 competitor sales numbers.

59:2 - 59:2 **Wong, Natalie 10-18-2016 (00:00:01)**

05_21_18 Combo Jones V9.36

59:2 Q. Well, that's an analysis --

59:5 - 59:7 **Wong, Natalie 10-18-2016 (00:00:07)**

05_21_18 Combo Jones V9.37

59:5 A. So I don't know if that rate is truly
 59:6 accurate when we compare our rates to our competitor
 59:7 rates.

59:8 - 59:18 **Wong, Natalie 10-18-2016 (00:00:22)**

05_21_18 Combo Jones V9.38

59:8 Q. That's analysis Bard does. Right?
 59:9 A. On a regular basis?
 59:10 Q. Well, no, I'm asking you, that's an
 59:11 analysis they do, right, they compare their rates to
 59:12 competitor rates?
 59:13 A. I -- when I worked on filters, yes, that's
 59:14 something we did compare.
 59:15 Q. And if that wasn't important, why would you
 59:16 do that calculation?
 59:17 A. We wanted to see how we compared to our
 59:18 competitors.

62:25 - 63:4 **Wong, Natalie 10-18-2016 (00:00:11)**

05_21_18 Combo Jones V9.43

62:25 Q. Ma'am, I'm handing you what has been marked
 63:1 as Deposition Exhibit 537.

WONG 537.1

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

Page/Line	Source	ID
63:2 - 63:7	63:2 Is that – is that an e-mail chain you've 63:3 seen before? 63:4 A. Yes. Wong, Natalie 10-18-2016 (00:00:06)	05_21_18 Combo Jones V9.41
63:5 - 63:15	63:5 Q. Is it an e-mail chain that was provided to 63:6 you by counsel in preparation for your deposition? 63:7 A. Yes. Wong, Natalie 10-18-2016 (00:00:08)	05_21_18 Combo Jones V9.42
63:12 - 63:15	63:12 So this is an e-mail from John Lehmann to 63:13 Robert Carr and Doug Uelmen, cc: Chris Ganser. 63:14 Correct? 63:15 A. Yes.	WONG 537.4.1
63:16 - 63:18	Wong, Natalie 10-18-2016 (00:00:07) 63:16 Q. Who are Robert Carr and Doug Uelmen? 63:17 A. Robert Carr was in R&D. Doug Uelmen was 63:18 the VP of quality.	05_21_18 Combo Jones V9.43
64:7 - 64:10	Wong, Natalie 10-18-2016 (00:00:06) 64:7 Q. And the subject 64:8 matter is "Draft data set for statistician." Did I 64:9 read that correctly? 64:10 A. Yes.	05_21_18 Combo Jones V9.44
68:5 - 68:7	Wong, Natalie 10-18-2016 (00:00:02) 68:5 Q. And that was sent to you on May 18th of 68:6 2004? 68:7 A. Yes.	05_21_18 Combo Jones V9.45
68:11 - 68:14	Wong, Natalie 10-18-2016 (00:00:05) 68:11 Q. What was the purpose of sending you this 68:12 data? 68:13 A. He wanted me to do a quick analysis of the 68:14 data.	05_21_18 Combo Jones V9.46
69:22 - 69:25	Wong, Natalie 10-18-2016 (00:00:08) 69:22 Q. And your ultimate conclusion there, 69:23 on May 20th of 2004 -- that's an e-mail from you. 69:24 Correct? 69:25 A. Yes.	05_21_18 Combo Jones V9.47
70:3 - 70:9	Wong, Natalie 10-18-2016 (00:00:16) 70:3 Q. And you said, "Doug, I've evaluated the 70:4 data comparing Recovery with the other products. 70:5 These results included quarter 2, 2004." Right? 70:6 A. Yes.	05_21_18 Combo Jones V9.48

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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70:7 Q. And you say, "Based on the limited amount
70:8 of data, the following can be concluded." Right?

70:9 A. Yes.

70:10 - 70:17

Wong, Natalie 10-18-2016 (00:00:23)

70:10 Q. And the first one is, there's not a
70:11 significant difference between the Recovery and the
70:12 TrapEase, OptEase, Greenfield, and VenaTech. Fair?

70:13 A. Yes.

70:14 Q. And that's -- but -- but you're careful to
70:15 say "at a 95 percent confidence interval." Right?

70:16 A. Well, I remember I was careful, because I
70:17 said that there was a limited amount of data.

71:7 - 71:14

Wong, Natalie 10-18-2016 (00:00:18)

71:7 Q. as for number two,
71:8 though, you say, "At a 95 percent confidence
71:9 interval, there is a significant difference between
71:10 Recovery and Glnther Tulip, Birds Nest, and SNF,"

71:11 A. Yes.

71:12 Q. Right?

71:13 And that significant difference is the
71:14 Recovery has a higher risk

71:14 - 71:17

Wong, Natalie 10-18-2016 (00:00:09)

71:14 associated with
71:15 it than those other filters. Right?

71:16 A. I think the math showed there was a
71:17 difference, yes.

71:21 - 72:1

Wong, Natalie 10-18-2016 (00:00:12)

71:21 Q. And the Glnther Tulip and the Birds
71:22 Nest, those are competitors of the Recovery. Right?

71:23 A. Yes.

71:24 Q. And the SNF is actually the predicate
71:25 device for the Recovery. Right?

72:1 A. Yes.

72:6 - 72:7

Wong, Natalie 10-18-2016 (00:00:08)

72:6 Q. The Recovery was not statistically
72:7 equivalent to the SNF, based on your calculations

72:9 - 72:10

Wong, Natalie 10-18-2016 (00:00:00)

72:9 Right?

72:10 A. Yes.

73:10 - 73:22

Wong, Natalie 10-18-2016 (00:00:37)

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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73:10 Q. And my question is, based on your
73:11 calculations here, would it be inaccurate to say that
73:12 the Recovery filter is better than the SNF filter.
73:13 Fair?

73:14 A. Yes.

73:15 Q. And it would be inaccurate to say it's --
73:16 it's the equivalent of the SNF filter?

73:17 A. I don't know, no.

73:18 Yes, they are not equivalent.

73:19 Q. The SNF --

73:20 A. If that was your question.

73:21 Q. Yeah, the -- the -- the Recovery filter is

73:22 worse than the SNF, based on your calculations

73:23 - 73:24 **Wong, Natalie 10-18-2016 (00:00:03)**

05_21_18 Combo Jones V9.53

73:23 Fair?

73:24 A. Based on the limited data, yes.

73:25 - 74:4 **Wong, Natalie 10-18-2016 (00:00:11)**

05_21_18 Combo Jones V9.57

73:25 Q. And that was the data you had

74:1 available. Right?

74:2 A. Right. And, normally, I wouldn't do this

74:3 analysis without more datapoints, which is why I said

74:4 "limited data," because I wasn't very confident.

77:7 - 77:8 **Wong, Natalie 10-18-2016 (00:00:02)**

05_21_18 Combo Jones V9.59

77:7 Q. And is that something that you think

77:8 physicians need to know?

77:12 - 77:20 **Wong, Natalie 10-18-2016 (00:00:26)**

05_21_18 Combo Jones V9.59

77:12 A. Yes.

77:13 Q. And is that something you're aware of ever

77:14 being provided to physicians?

77:15 A. That I don't know.

77:16 Q. And, based on your calculations, let's look

77:17 at page -- let's look at this chart that you did, the

77:18 Product Statistical Summary chart. Do you see where

77:19 I'm looking?

77:20 A. Yes.

78:1 - 78:4 **Wong, Natalie 10-18-2016 (00:00:14)**

05_21_18 Combo Jones V9.60

78:1 Q. And despite not finding statistical

78:2 significance with regards to any of the other

78:3 filters, none of the other filters had even half of

78:4 the -- the adverse

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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78:4 - 78:7

Wong, Natalie 10-18-2016 (00:00:07)

05_21_18 Combo Jones V9.01

78:4 average that the

78:5 Recovery did. Fair?

78:6 A. Yes. Based on the data provided.

WONG 917.2.4

78:7 Q. And the Recovery had a higher average

78:8 - 78:21

Wong, Natalie 10-18-2016 (00:00:30)

05_21_18 Combo Jones V9.02

78:8 associated with those filters than any of the

78:9 other filters that you did the calculation for?

78:10 A. Yes.

78:11 Q. At least twice as much?

78:12 A. Yes.

WONG 917.7.5

78:13 Q. And with regard to the SNF, the average was

78:14 literally zero. Right?

78:15 A. Yes.

Jtrial

78:16 Q. And that was the predicate device for the

78:17 Recovery?

78:18 A. Yes.

78:19 Q. And the Recovery is -- the Recovery is

78:20 certainly not equivalent to or better than the SNF,

78:21 fair, in this issue?

78:23 - 78:24

Wong, Natalie 10-18-2016 (00:00:05)

05_21_18 Combo Jones V9.03

78:23 THE WITNESS: Just based on these numbers,

78:24 no, they're not equivalent.

79:2 - 79:9

Wong, Natalie 10-18-2016 (00:00:24)

05_21_18 Combo Jones V9.04

79:2 Q. And what was this chart used for?

79:3 A. I don't know what was -- what it was used

79:4 for. I summarize what I was looking at to provide to

79:5 Doug, but it --

79:6 Q. And it was for -- oh, sorry, go ahead.

79:7 A. You know, the number of samples for this

79:8 data analysis was really low. Typically, we want 30

79:9 samples to do --

79:25 - 80:4

Wong, Natalie 10-18-2016 (00:00:16)

05_21_18 Combo Jones V9.05

79:25 Q. But, just by your calculation, it

80:1 wasn't statistically significant, within a 95 percent

80:2 confidence interval?

80:3 A. To calculate statistical significance,

80:4 usually you need around 30 samples.

83:1 - 83:4

Wong, Natalie 10-18-2016 (00:00:14)

05_21_18 Combo Jones V9.06

83:1 Q. To calculate the percent failure?

Jtrial

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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109:24 - 110:3	<p>83:2 A. I couldn't -- yeah, I couldn't predict the</p> <p>83:3 percent failure, because I think I needed more</p> <p>83:4 datapoints to help with analysis of it.</p> <p>Wong, Natalie 10-18-2016 (00:00:15)</p> <p>109:24 Q. All right, ma'am, I'm handing you what's</p> <p>109:25 been marked as Deposition Exhibit 540. And this is</p> <p>110:1 titled -- this is a June 20th, 2006 "Recovery</p> <p>110:2 Fracture and Migration Complaint Update." Correct?</p> <p>110:3 A. Yes.</p>	<p>05_21_18 Combo Jones V9 67</p> <p>WONG 510.1</p> <p>WONG 510.1.1</p>
110:7 - 110:9	<p>Wong, Natalie 10-18-2016 (00:00:06)</p> <p>110:7 Q. Is this something that you would have</p> <p>110:8 prepared?</p> <p>110:9 A. Yes. Let me flip through real quick. Yes.</p>	<p>05_21_18 Combo Jones V9 68</p> <p>110.07</p>
111:16 - 111:21	<p>Wong, Natalie 10-18-2016 (00:00:18)</p> <p>111:16 Q. and if we look at SNF, SNF had</p> <p>111:17 three filter fractures in 84,520 units sold. Right?</p> <p>111:18 A. Yes.</p> <p>111:19 Q. Versus the Recovery had 66 fractures in</p> <p>111:20 only 34,467 units sold. Right?</p> <p>111:21 A. Yes.</p>	<p>05_21_18 Combo Jones V9 69</p> <p>WONG 510.27</p>
114:18 - 114:20	<p>Wong, Natalie 10-18-2016 (00:00:07)</p> <p>114:18 A. Okay. So this table is comparing the</p> <p>114:19 complaints that we have received and comparing it</p> <p>114:20 against the DFMEA rankings.</p>	<p>05_21_18 Combo Jones V9 109</p> <p>114.18</p>
120:16 - 120:20	<p>Wong, Natalie 10-18-2016 (00:00:13)</p> <p>120:16 Q. You don't think it's important that an</p> <p>120:17 internal Bard analysis finding an undesirable risk</p> <p>120:18 assessment ranking for -- for fracture with regard to</p> <p>120:19 the Recovery is something that physicians and</p> <p>120:20 patients need to know about?</p>	<p>05_21_18 Combo Jones V9 70</p> <p>120.16</p>
120:22 - 120:22	<p>Wong, Natalie 10-18-2016 (00:00:06)</p> <p>120:22 THE WITNESS: I don't know.</p>	<p>05_21_18 Combo Jones V9 71</p>
121:15 - 121:16	<p>Wong, Natalie 10-18-2016 (00:00:02)</p> <p>121:15 THE WITNESS: I think physicians should</p> <p>121:16 know.</p>	<p>05_21_18 Combo Jones V9 72</p>
129:1 - 129:9	<p>Wong, Natalie 10-18-2016 (00:00:23)</p> <p>129:1 Q. So if this is not an</p> <p>129:2 acceptable rate then why is it being used -- why is</p> <p>129:3 it included here as -- why is it relevant?</p> <p>129:4 A. It's a comparison.</p>	<p>05_21_18 Combo Jones V9 73</p> <p>129.01</p>

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129:5 Q. Why compare something you don't think is
129:6 acceptable?

129:7 A. It was accepted by industry for the SIR
129:8 guidelines. We were just comparing our numbers to
129:9 what those rates were in that article.

130:19 - 130:19 **Wong, Natalie 10-18-2016 (00:00:01)**

05_21_18 Combo Jones V9.74

130:19 Q. Is that significant?

130:21 - 130:22 **Wong, Natalie 10-18-2016 (00:00:06)**

05_21_18 Combo Jones V9.75

130:21 THE WITNESS: It's higher. I don't know if
130:22 it's statistically significant. It is higher.

131:7 - 131:12 **Wong, Natalie 10-18-2016 (00:00:18)**

05_21_18 Combo Jones V9.76

131:7 It's not accurate to say that the RNF was
131:8 an improvement on the SNF with regard to fracture.
131:9 Fair?

131:10 A. I don't know. SNF is a permanent filter,
131:11 Recovery's retrievable. So the true rate of fracture
131:12 on a SNF, I don't know what that is.

135:3 - 135:13 **Wong, Natalie 10-18-2016 (00:00:41)**

05_21_18 Combo Jones V9.77

135:3 Q. What is being marked as Deposition Exhibit
135:4 542.

V0100 542.1

135:5 A. Thank you.

135:6 Q. And this is an e-mail exchange between you
135:7 and Sandy Kerns, on December 2nd of 2009. Correct?
135:8 A. Yes. I was in field assurance at the time.

W0102 542.1.1

135:9 Q. And who is Sandy Kerns?

135:10 A. She's a field assurance coordinator.

135:11 Q. Okay. And she e-mails you and says "How
135:12 many filters fractures were in November?" Right?

V0100 542.1.2

135:13 A. Yes.

135:18 - 136:5 **Wong, Natalie 10-18-2016 (00:00:36)**

05_21_18 Combo Jones V9.78

135:18 Q. And your -- your response was "19."

W0100 542.1.3

135:19 Correct?

135:20 A. Yes.

135:21 Q. That means there was 19 filter fractures
135:22 reported in November of 2009 --

135:23 A. Yes.

135:24 Q. -- is that right?

135:25 Is 19 a lot of fractures for a month?

136:1 A. I don't remember. It sounds like a lot.

518.00

136:2 Q. Well, if there was 19 reported for one

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136:3 month, over the course of a year, that extrapolates
 136:4 to 221. Right?
 136:5 A. Yeah, around that.

136:10 - 136:13 **Wong, Natalie 10-18-2016 (00:00:07)**
 136:10 Q. It sounds like you're
 136:11 right, because Sandy's response is "youch." Correct?
 136:12 A. Uh-huh. Yup.

136:15 - 136:15 **Wong, Natalie 10-18-2016 (00:00:02)**
 136:15 THE WITNESS: That it's a lot for a month.

136:17 - 137:4 **Wong, Natalie 10-18-2016 (00:00:37)**
 136:17 Q. what was done within Bard about
 136:18 the fact that there was 19 filter fractures reported
 136:19 in a single month?
 136:20 A. I don't know. I mean, I would have to look
 136:21 at what those 19 were. I don't know -- I don't
 136:22 recall, from 2009, if there was a trend.
 136:23 Q. Okay. If you're -- if Bard is seeing
 136:24 something like 19 filter fractures in a single month,
 136:25 is -- how would they let physicians or patients know
 137:1 about this?
 137:2 A. They wouldn't let physicians or patients
 137:3 know yet. I think we would look at the 19 and
 137:4 understand why there were 19.

140:5 - 140:10 **Wong, Natalie 10-18-2016 (00:00:12)**
 140:5 Q. At what point in the process would -- would
 140:6 physicians and patients be made aware of a spike in
 140:7 fractures?
 140:8 A. If it was a true spike, and we couldn't
 140:9 explain it, it would go down the investigation
 140:10 pathway.

141:17 - 142:6 **Wong, Natalie 10-18-2016 (00:00:46)**
 141:17 Q. And do you have 543 in front of you?
 141:18 A. Yes.
 141:19 Q. And this is an e-mail from you to several
 141:20 people attaching a presentation on caudal migration.
 141:21 Correct?
 141:22 A. Yes, for G2.
 141:23 Q. Yeah, excuse me, for G2. And it's dated
 141:24 March 2nd of 2006?

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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141:25 A. Yes.

142:1 Q. And was this something you prepared?

142:2 A. Yes.

142:3 Q. And you were actually the lead investigator

142:4 on the G2 caudal migration failure investigations

142:5 report. Right?

142:6 A. Yes. With the support of my team.

145:19 - 145:22 **Wong, Natalie 10-18-2016 (00:00:08)**

05_21_18 Combo Jones V9 66

145:19 Q. And now look at the next page, if you

145:20 would. Here we've got "G2 Compared to SNF and RNF,"

145:21 is the heading. Right?

145:22 A. Yes.

WONG 543 9

146:14 - 146:20 **Wong, Natalie 10-18-2016 (00:00:37)**

05_21_18 Combo Jones V9 66

47527

146:14 Q. And fair to say that the Recovery is more

146:15 resistant to caudal migration than the G2?

146:16 A. Yeah, I don't think we had that many

146:17 reports of caudal migration with Recovery.

146:18 Q. And the SNF is, given that it had zero

146:19 caudal migrations reported, it's certainly more

146:20 resistant to caudal migration than the G2. Correct?

146:22 - 146:23 **Wong, Natalie 10-18-2016 (00:00:03)**

05_21_18 Combo Jones V9 66

146:22 THE WITNESS: Yes, there were no caudal

146:23 migrations of the SNF.

148:6 - 148:10 **Wong, Natalie 10-18-2016 (00:00:16)**

05_21_18 Combo Jones V9 67

148:6 Q. And it would be -- based on the data

148:7 that's -- the available data that's in this

148:8 spreadsheet, it would be inaccurate to say that the

148:9 G2 was more stable than the -- than the RNF.

148:10 Correct?

148:12 - 148:12 **Wong, Natalie 10-18-2016 (00:00:05)**

05_21_18 Combo Jones V9 68

148:12 THE WITNESS: Yes.

151:19 - 152:9 **Wong, Natalie 10-18-2016 (00:00:50)**

05_21_18 Combo Jones V9 69

WONG 543 16

151:19 Q. Okay. Look at the next page, if you would.

151:20 This is the caudal severity description. And I'm

151:21 looking at type III and type IV. Caudal migration

151:22 can be -- can result in a reintervention to remove

151:23 the filter. Right?

151:24 A. Yes, for -- for the type III.

151:25 Q. And, yeah, and caudal migration can result

152:1 in the need to repair damage to a patient's anatomy?

WONG 543 16.1

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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152:2 A. Yes.

152:3 Q. And caudal migration can result in patient

WONG 543 14.4

152:4 injury?

152:5 A. Yes.

152:6 Q. And caudal migration can result in a filter

WONG 543 15.6

152:7 no longer providing its primary function of -- of

152:8 protection from pulmonary embolism?

152:9 A. Yes.

05_21_18 Combo Jones V9.90

153:13 - 153:17 **Wong, Natalie 10-18-2016 (00:00:09)**

153:13 Q. And caudal migration can result in -- in

153:14 death, correct, according to the type IV?

WONG 543 16.8

153:15 A. Yes.

153:16 Q. And life-threatening injury?

WONG 543 17.8

153:17 A. Yes.

05_21_18 Combo Jones V9.91

154:8 - 156:3 **Wong, Natalie 10-18-2016 (00:02:28)**

154:8 Q. Okay. Well, the -- the ultimate ranking on

WONG 543 19.1

154:9 this, and you -- it's in a red box, pointing to quad

154:10 level states, that for type III and type IV the quad

154:11 level was, "Unacceptable risk per FMEA, type III

154:12 above threshold." Correct?

154:13 A. Yes, that's what it says.

154:14 Q. And -- and what does that mean?

154:15 A. So it's saying, with the severity that's

154:16 been established with our complaint rate, that our --

154:17 that for type III, it's above the threshold of .05

154:18 percent.

154:19 Q. And so if you look down in the -- in the

WONG 543 20.2

154:20 left-hand corner, it -- if you look at quad versus

154:21 detection ranking, B says, Quad 3 or 4, which we've

154:22 got, right? It's a Quad 3 or 4, isn't it, type III

154:23 or type --

154:24 A. Sorry, yes.

154:25 Q. And then it says "with detection of three

155:1 to five" -- and we've got detection of five,

155:2 Correct?

155:3 A. Yes.

155:4 Q. -- "requires recommended action prior to

155:5 product release." Right?

155:6 A. Yes.

155:7 Q. And in this case, the G2 has already been

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155:8 released. Right?

155:9 A. Right.

155:10 Q. And so what was done to inform patients and

155:11 physicians that additional recommend -- that

155:12 additional actions were needed, and that there was an

155:13 unacceptable risk?

155:14 A. There was no communication.

155:15 Q. Why not?

155:16 A. Because I think when we started

155:17 investigating this, there were 13 and we're still

155:18 investigating why we haven't gone through the whole

155:19 investigation process yet.

155:20 Q. But you've got a -- you've got a product

155:21 that's already on the market. Right?

155:22 A. Yes.

155:23 Q. And you've got an unacceptable risk per

155:24 Bard's internal FMEA analysis. Right?

155:25 A. Through this analysis, yes.

156:1 Q. And you've got -- and -- and that requires

156:2 action to be taken by Bard. Correct?

156:3 A. Yes.

156:19 - 157:3 **Wong, Natalie 10-18-2016 (00:00:32)**

156:19 Q. You've had 13 complaints in 8,000 sales

156:20 with this -- with this G2 filter of caudal migration,

156:21 and only three in over 30,000 with the RNF. Right?

156:22 A. Right.

156:23 Q. So that's -- that's trending in a bad

156:24 direction for -- with regard to caudal migration.

156:25 Fair?

157:1 A. Yes, but it's also limited data, because

157:2 when I put the summary together, I think we're four

157:3 months.

157:11 - 157:15 **Wong, Natalie 10-18-2016 (00:00:26)**

157:11 Q. And type III includes that "the filter is

157:12 no longer providing primary function of protection

157:13 from PE," right? Or a perforation or an injury.

157:14 Correct?

157:15 A. Yes.

157:16 - 157:21 **Wong, Natalie 10-18-2016 (00:00:19)**

157:16 Q. So this is -- this is a relatively

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157:17 significant typing, right, I mean, type III is the

157:18 second -- second to highest?

157:19 A. If the complaint came in and if -- and

157:20 if -- it was any one of those three, being

157:21 conservative, we'd marked it as a type III.

158:7 - 158:25

Wong, Natalie 10-18-2016 (00:00:50)

05_21_18 Combo Jones V9.55

158:7 Q. So even under Bard's own analysis,

158:8 the G2 caudal migration risk was unacceptable as of

158:9 this date?

158:10 A. Unacceptable -- unacceptable per the FMEA.

158:11 Q. Which is Bard's internal analysis.

158:12 Correct?

158:13 A. Yes.

158:14 Q. Now, looking at the next page, this is the

158:15 R002 ranking. Correct?

158:16 A. Yes.

W09.07.112.21.2

158:17 Q. And it ranks type III migrations as a

158:18 potential severity of critical. Right?

158:19 A. Yes.

158:20 Q. And critical means, "A failure that can

158:21 contribute to death, severe injury, permanent

158:22 significant disability or severe occupational illness

158:23 in a patient or device user."

158:24 Did I read that correctly?

158:25 A. Yes.

160:12 - 160:14

Wong, Natalie 10-18-2016 (00:00:07)

05_21_18 Combo Jones V9.56

160:12 MR. DEGREEFF: All right. I'm handing you

160:13 what's being marked as Deposition Exhibit 544, I

160:14 believe.

11/1/16

160:17 - 160:22

Wong, Natalie 10-18-2016 (00:00:17)

05_21_18 Combo Jones V9.57

160:17 Q. And this is an e-mail from you to a bunch

160:18 of people. Right?

160:19 A. Yes.

160:20 Q. And you are providing documents for a

160:21 meeting on May 18th of 2006?

160:22 A. Yes.

164:9 - 164:13

Wong, Natalie 10-18-2016 (00:00:17)

05_21_18 Combo Jones V9.58

164:9 Q. Well, as of April 28th, 2006, in your

164:10 memorandum right here is a statement about how to

164:11 prevent caudal migration. Correct?

W09.05.041.1.1

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	164:12 A. It's a statement of what Greenfield did to	WONG 041 2 2
	164:13 prevent caudal migration.	
164:14 - 164:15	Wong, Natalie 10-18-2016 (00:00:01)	05_21_18 Combo Jones V9 101
	164:14 Q. and that worked for	010 10
	164:15 Greenfield. Fair?	
164:17 - 164:17	Wong, Natalie 10-18-2016 (00:00:01)	05_21_18 Combo Jones V9 102
	164:17 THE WITNESS: That I don't know.	
164:19 - 164:23	Wong, Natalie 10-18-2016 (00:00:21)	05_21_18 Combo Jones V9 103
	164:19 Q. Well, if you have this as an -- as an	
	164:20 option in 2006, and this is what was ultimately done	
	164:21 on the Meridian, why did it take over five years to	
	164:22 release a product with caudal anchors?	
	164:23 A. I don't know. I wasn't on the team.	05_21_18 Combo Jones V9 102
167:18 - 167:20	Wong, Natalie 10-18-2016 (00:00:02)	
	167:18 Q. Aren't you a -- a part of new product	
	167:19 development?	
	167:20 A. Yes.	05_21_18 Combo Jones V9 103
167:22 - 168:2	Wong, Natalie 10-18-2016 (00:00:18)	
	167:22 do you not have an	
	167:23 understanding of how long it should take to -- to	
	167:24 make a change to a product?	
	167:25 A. I have an understanding of the steps we	
	168:1 need to release a product, but for an implant, like a	
	168:2 filter, I don't know what is a reasonable time frame.	05_21_18 Combo Jones V9 104
168:9 - 168:16	Wong, Natalie 10-18-2016 (00:00:23)	
	168:9 Q. I mean, you can literally get a new device	
	168:10 up and running with the bench testing and everything	
	168:11 else in less than five years?	
	168:12 A. I don't know. I don't know what new test	
	168:13 methods we would have needed to develop during that	
	168:14 time frame. I don't know the animal studies that we	
	168:15 would need to do. I don't know. I wasn't part of	
	168:16 filter development.	05_21_18 Combo Jones V9 105
168:22 - 168:24	Wong, Natalie 10-18-2016 (00:00:07)	
	168:22 Q. And this was essentially the -- Meridian	
	168:23 was essentially the same product with caudal anchors	
	168:24 added. Correct?	05_21_18 Combo Jones V9 106
169:1 - 169:2	Wong, Natalie 10-18-2016 (00:00:02)	
	169:1 THE WITNESS: I don't know. I was not on	
	169:2 Meridian.	

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170:6 - 170:12	Wong, Natalie 10-18-2016 (00:00:15) 170:6 Q. you've been handed what's 170:7 marked as Deposition -- and I have no idea -- can you 170:8 tell us what the number is? 170:9 A. 545. 170:10 Q. Okay. And this is an e-mail from you to 170:11 Gin Schulz on July 13th of 2006. Correct? 170:12 A. Yes.	05_21_18 Combo Jones V9.107 WONG 545.1 WONG 545.1 05_21_18 Combo Jones V9.108
170:19 - 170:23	Wong, Natalie 10-18-2016 (00:00:17) 170:19 Q. Okay. And if you look on page 2 of 15 of 170:20 the caudal migration, it lists -- it lists -- under 170:21 2.0 it lists you as the primary investigator. 170:22 Correct? 170:23 A. Yes.	WONG 545.1 05_21_18 Combo Jones V9.109
176:7 - 176:10	Wong, Natalie 10-18-2016 (00:00:12) 176:7 Q. So, per Bard's -- per Bard's rationale in 176:8 this -- in this failure investigation report, the 176:9 over -- the -- a caudal migration represents a 176:10 significant risk. Fair?	05_21_18 Combo Jones V9.110
176:12 - 176:13	Wong, Natalie 10-18-2016 (00:00:03) 176:12 THE WITNESS: Per the DFMEA, it's a 176:13 Quad 3 significant risk.	05_21_18 Combo Jones V9.111
178:18 - 178:20	Wong, Natalie 10-18-2016 (00:00:04) 178:18 Q. During your time on the G2 filter, was a 178:19 root cause ever identified? 178:20 A. No.	05_21_18 Combo Jones V9.112
179:4 - 179:13	Wong, Natalie 10-18-2016 (00:00:25) 179:4 Q. If you look down at -- at 10.3, it says 179:5 "Preventative Action." 179:6 A. Yes. 179:7 Q. Under that it says, "none." 179:8 A. Yes. 179:9 Q. So Bard essentially opted to do nothing 179:10 with regard to preventative action on the caudal 179:11 migration? 179:12 A. No preventative actions, but there were 179:13 corrective actions.	WONG 545.15.2 05_21_18 Combo Jones V9.113
179:19 - 179:22	Wong, Natalie 10-18-2016 (00:00:06) 179:19 Q. that doesn't help any, any 179:20 physicians or patients, unless they're told about the	05_21_18 Combo Jones V9.113

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179:21 issue. Right?
 179:22 A. Yes.

181:11 - 181:14 **Wong, Natalie 10-18-2016 (00:00:06)**
 181:11 Q. what they decided
 181:12 to do with regard to remedial action and preventative
 181:13 action was nothing. Right?
 181:14 A. At this time, no.

181:18 - 181:22 **Wong, Natalie 10-18-2016 (00:00:11)**
 181:18 Q. Preventative actions and remedial actions
 181:19 would be something that done outside of the company
 181:20 to actually try to -- try to prevent injuries from
 181:21 occurring?
 181:22 A. Yes. There were none.

184:6 - 185:5 **Wong, Natalie 10-18-2016 (00:01:08)**
 184:6 Q. So does this mean that the G2,
 184:7 percentagewise, had a greater number of leg
 184:8 detachments than the RNF?
 184:9 A. Yes.
 184:10 Q. And then if you look down further
 184:11 there's -- it says, "Caudal migration." Correct?
 184:12 A. Yes.
 184:13 Q. G2, 14 percent; RNF, 3 percent?
 184:14 A. Yes.
 184:15 Q. Comments says, "G2 more caudal than RNF"?
 184:16 A. Yes.
 184:17 Q. And this is in November 30th of 2008.
 184:18 Correct?
 184:19 A. Yes.
 184:20 Q. And this was -- this increased rate of
 184:21 caudal migration with the G2 versus the RNF is
 184:22 consistent with everything we looked at in your 2006
 184:23 PowerPoints also. Right?
 184:24 A. Yes, G2 had more caudal than RNF, yes.
 184:25 Q. And caudal migration is an aspect of
 185:1 stability of the filter. Fair?
 185:2 A. Yes.
 185:3 Q. So would it be inaccurate to say that the
 185:4 G2 had increased stability over the Recovery?
 185:5 A. I don't know.

185:6 - 186:7 **Wong, Natalie 10-18-2016 (00:01:27)**

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185:6 Q. Well, certainly, with regard to caudal
 185:7 migration, it lacks stability in comparison to the
 185:8 Recovery. Correct?
 185:9 A. In the caudal migration direction.
 185:10 Q. Okay. Well, look at the next one down,
 185:11 cephalad migration, that's -- that's towards the
 185:12 head. Correct?
 185:13 A. Yes.
 185:14 Q. And you've got the G2 and the RNF both have
 185:15 4 percent migration rate, right, cephalad migration
 185:16 rate?
 185:17 A. Yes.
 185:18 Q. And the comment is "same." Correct?
 185:19 A. Yes, I'm just confused, though, with this
 185:20 chart.
 185:21 Q. Well, so you're looking at -- you've got
 185:22 the G2 has a higher rate of migration, of caudal
 185:23 migration rate than the RNF. Right?
 185:24 A. Yes, but I think it might be relative to
 185:25 filter fracture.
 186:1 Q. Well, there's -- there's a separate line
 186:2 item in here that deals with limb detachments.
 186:3 Right?
 186:4 A. Yes, but this packet is for G2 and G2X
 186:5 fracture analysis. So I think these are fractures.
 186:6 And of those fractures, how many were caudal
 186:7 migration in association with the fracture.

191:8 - 191:23

Wong, Natalie 10-18-2016 (00:00:33)

191:8 Q. You're going to be handed what's been
 191:9 marked as Deposition Exhibit 547. Have you got that
 191:10 in front of you?
 191:11 A. Yes.
 191:12 Q. And if you look at the very top, there's an
 191:13 e-mail from you to Brian Hudson with the subject
 191:14 line, "FDA Request for Information." Correct?
 191:15 A. Yes.
 191:16 Q. And the date is May 9th of 2006?
 191:17 A. Yes.
 191:18 Q. And there are some attachments to that. It
 191:19 looks like three different attachments?

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191:20 A. Yes.

191:21 Q. And your e-mail says, "Please see

191:22 attached"?

191:23 A. Yes.

201:5 - 201:15

Wong, Natalie 10-18-2016 (00:00:27)

05_21_18 Combo Jones V9.114

201:5 Q. it's your understanding of the

201:6 SIR guidelines as the -- one of the people that's in

201:7 new product development and a member of the quality

201:8 engineering team, that the SIR guidelines represent a

201:9 threshold for migra -- for caudal migration?

201:10 A. There's threshold numbers in the SIR

201:11 guidelines, but we set our own internal threshold to

201:12 be lower than that.

201:13 Q. You set your own internal threshold lower

201:14 than the SIR guidelines?

201:15 A. Yeah, which -- yeah.

201:16 - 202:11

Wong, Natalie 10-18-2016 (00:01:06)

05_21_18 Combo Jones V9.119

201:16 Q. Then why would Bard

201:17 tell the FDA that the SIR thresh -- SIR guidelines

201:18 thresholds were -- were important?

201:19 A. Because I think that's what was out there

201:20 in industry was this SIR guidelines.

201:21 Q. Isn't it more likely that it's because Bard

201:22 failed its own internal threshold, so it had to come

201:23 up with some threshold that it passed?

201:24 A. I don't know.

201:25 Q. That's certainly possible, isn't it?

202:1 A. It is possible, but I think the SIR

202:2 guidelines are what industry was saying is clinically

202:3 relevant threshold percentage.

202:4 Q. And if you look at -- so, there was a

202:5 threshold of 2 percent, as reported to the FDA here?

202:6 You see the threshold -- movement migration,

202:7 threshold from SIR guidelines 2 percent?

202:8 A. Yes.

202:9 Q. That would mean it was acceptable for 1 in

202:10 50 -- for 1 in 50 filters to migrate. Right?

202:11 A. Yes, per the guidelines.

202:12 - 202:15

Wong, Natalie 10-18-2016 (00:00:14)

05_21_18 Combo Jones V9.120

202:12 Q. Does that sound acceptable to you?

05_21_18

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202:13 A. I don't know. It's -- I think it's up to
 202:14 the physician to under -- to determine what's
 202:15 significantly -- what's a significant migration.

202:18 - 203:8 **Wong, Natalie 10-18-2016 (00:00:35)**
 202:18 Q. My question is, does 1 in 50 filter
 202:19 migrations sound like something that Bard would deem
 202:20 acceptable?
 202:21 A. No.
 202:22 Q. But -- but here Bard is telling the FDA
 202:23 that's an acceptable threshold?
 202:24 A. From industry guidelines, SIR guidelines.
 202:25 Q. Yeah, but Bard --
 203:1 A. But we're not close to that number, we're
 203:2 at .129 percent.
 203:3 Q. Yeah, but my question is, I mean, here Bard
 203:4 is telling the FDA that a clinically relevant
 203:5 threshold for migration is 2 percent, but yet
 203:6 internally applying a much stricter threshold.
 203:7 Right?
 203:8 A. Yes.

203:9 - 203:14 **Wong, Natalie 10-18-2016 (00:00:17)**
 203:9 Q. Why would you need to pass
 203:10 on that -- that 2 percent threshold to the FDA,
 203:11 unless it was because Bard didn't pass its own
 203:12 internal thresholds?
 203:13 A. I mean, I know we set our -- ours more
 203:14 rigorous.

204:1 - 205:2 **Wong, Natalie 10-18-2016 (00:01:13)**
 204:1 Q. Well, let's look at the next
 204:2 paragraph down, it says, "Per table 1 above, BPV's
 204:3 overall migration rate is within the range of
 204:4 reported (0 to 18 percent), and below the threshold
 204:5 (2 percent) rates, as described in the SIR quality
 204:6 improvement guidelines. In conclusion, the G2 filter
 204:7 migration rate is below the risk threshold per BPV's
 204:8 internal risk management system, and is below the
 204:9 event rates and threshold reported in the SIR quality
 204:10 improvement guidelines."
 204:11 Did I read that correctly?
 204:12 A. Yes.

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05_21_18 Combo Jones V9 122

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204:13 Q. So Bard is certainly using the
204:14 SIR threshold here as the threshold -- one of the
204:15 threshold rates that it is better than. Correct?

204:16 A. Yes.

204:17 Q. But yet it's not using that internally as a
204:18 threshold. Right?

204:19 A. No.

204:20 Q. And Bard would never consider 1 in 50
204:21 filters migrating to be -- to be a reasonable
204:22 standard, would they?

204:23 A. No, which is why we set ours lower.

204:24 Q. Okay. And it then says that Bard's G2
204:25 filter migration rate is below the risk threshold per
205:1 its risk management system. Right?

205:2 A. Yes.

205:3 - 205:8

Wong, Natalie 10-18-2016 (00:00:15)

205:3 Q. Well, that's not right. I know -- we know
205:4 that it -- we know that it initially failed it until
205:5 it did the reassessment. Right?

205:6 A. But I need to look at the DFMEA, to see if
205:7 we increased our overall risk profile, because I -- I
205:8 can't derive that from this paragraph.

206:2 - 206:10

Wong, Natalie 10-18-2016 (00:00:19)

206:2 Q. But it's cool, because we reassessed.
206:3 Right?

206:4 A. No, it's not. We reevaluated it, but I
206:5 need to see that DFMEA to see what that means.

206:6 Q. As you sit here as the person who was in
206:7 charge of the G2 caudal migration failure
206:8 investigation, you don't remember anything about
206:9 that?

206:10 A. I need to go back to the document.

206:15 - 206:15

Wong, Natalie 10-18-2016 (00:00:01)

206:15 Q. what they say here is,

206:18 - 206:22

Wong, Natalie 10-18-2016 (00:00:19)

206:18 "design failure modes and effects analysis
206:19 for this product, the expected frequency of
206:20 occurrence for a cephalad migration, resulting in an
206:21 effect (i.e., severity) similar to this complaint, is
206:22 less than or equal to .05 percent."

05_21_18 Combo Jones V9-Wong 10-18-16 Jones Trial Designations V9

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206:24 - 207:3	Wong, Natalie 10-18-2016 (00:00:10) 206:24 A. Yes. 206:25 Q. And it then says "The observed frequency of 207:1 occurrence is .016 percent as of April 30th, 2006." 207:2 Right? 207:3 A. Yes.	05_21_18 Combo Jones V9.128 WONG 647.7.3
214:2 - 214:10	Wong, Natalie 10-18-2016 (00:00:20) 214:2 Q. There was nothing done to the G2X to 214:3 improve its potential for complications, like tilt, 214:4 fracture, migration, perforation, things like that. 214:5 Correct? 214:6 A. Correct. 214:7 Q. So it makes sense to combine those two 214:8 devices in doing an analysis of not just fractures, 214:9 but other complications. True? 214:10 A. Yes.	05_21_18 Combo Jones V9.130 CH 12
249:13 - 250:9	Wong, Natalie 10-18-2016 (00:01:13) 249:13 Q. Okay. 549 is an e-mail -- well, it 249:14 actually is -- yes, it is an e-mail, dated May 27, 249:15 2004 from Natalie Wong to Doug Uelmen. Does this 249:16 help refresh your recollection as to whether or not 249:17 you might have actually gotten more involved in this 249:18 analysis and procedure than after May 21? 249:19 A. I think -- yeah, I remember -- I remember 249:20 seeing this e-mail now. 249:21 Q. And you wrote -- and you wrote this e-mail 249:22 to Mr. Uelmen on May 27, 2004? 249:23 A. Yes. 249:24 Q. And it's -- the subject matter is Recovery 249:25 stats. Right? 250:1 A. Yes. 250:2 Q. And do you see where you report to Doug 250:3 that you're "using the criteria you indicated this 250:4 morning," meaning Doug. Right? 250:5 A. Yes. 250:6 Q. "I have evaluated the data." Right? 250:7 A. Yes. 250:8 Q. So he's having you evaluate more data? 250:9 A. Yes.	05_21_18 Combo Jones V9.137
253:11 - 253:15	Wong, Natalie 10-18-2016 (00:00:10)	05_21_18 Combo Jones V9.139

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253:11	Q. So as more data's coming in, you're	
253:12	being provided -- you're using the same computer	
253:13	program to see if you can come up with statistical	
253:14	significance, 95 percent confidence level. True?	
253:15	A. Yes.	
254:21 - 255:14	Wong, Natalie 10-18-2016 (00:00:46)	05_21_18 Combo Jones V9 133
254:21	Q. I mean, did you know as of May of	
254:22	2004, they were actually in the process of	
254:23	redesigning the Recovery filter because they knew	
254:24	they had a crisis with respect to its propensity to	
254:25	migrate and fracture?	
255:1	A. I didn't know that at that point.	
255:2	Q. You found that out at some point. Right?	
255:3	A. Yeah, some point later.	
255:4	Q. That this thing was not designed to take	
255:5	care of the type of -- type of clots that it was	
255:6	designed to take care of. You learned that. Right?	
255:7	A. Yes.	
255:8	Q. But yet it continued to sell the product,	
255:9	knowing that it had design issues and failures.	
255:10	True?	
255:11	A. Yes.	
255:12	Q. And it didn't stop until it had the G2	
255:13	filter available to -- to market?	
255:14	A. Yes.	
257:2 - 257:10	Wong, Natalie 10-18-2016 (00:00:23)	05_21_18 Combo Jones V9 140
257:2	Q. So then, as of May 27, 2004, the Recovery's	
257:3	reporting rate for death events was statistically	
257:4	significantly higher than five of the seven other	
257:5	filters on the market. Right? True?	
257:6	A. Compared to five --	
257:7	Q. Five other --	
257:8	A. Yes.	
257:9	Q. Five other devices on the market?	
257:10	A. Yes.	
283:12 - 283:12	Wong, Natalie 10-18-2016 (00:00:03)	05_21_18 Combo Jones V9 141
283:12	THE REPORTER: 552.	
283:15 - 283:22	Wong, Natalie 10-18-2016 (00:00:16)	05_21_18 Combo Jones V9 142
283:15	Q. Do you recognize this document?	
283:16	A. In general, yes.	

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283:17 Q. Okay. And this is you here. Right?

283:18 A. Yes.

283:19 Q. This is a memorandum you prepared?

283:20 A. Along with Micky, yes.

283:21 Q. With Micky Graves. Who is Micky Graves?

283:22 A. He's an R&D engineer.

287:20 - 287:23 **Wong, Natalie 10-18-2016 (00:00:06)**

05_21_18 Combo Jones V9.143

287:20 Q. So somebody asked you for the data

287:21 comparing the Recovery filter to the Simon Nitinol

287:22 filter. Right?

287:23 A. Yes.

288:19 - 289:3 **Wong, Natalie 10-18-2016 (00:00:30)**

05_21_18 Combo Jones V9.144

288:19 Q. And you determined that as of January 31,

288:20 '06, that in the lifetime of the Recovery filter,

288:21 there were 95 fractures, including one in a clinical

288:22 trial, and the Simon Nitinol filter as of the third

288:23 quarter of 2005 had three fractures. Right?

288:24 A. Yes.

288:25 Q. And the Simon Nitinol filter had been on

289:1 the market for at least 10 years longer than the

289:2 Recovery filter. Right?

289:3 A. I don't remember.

Plaintiffs Designations = 00:24:46

Defense Designations = 00:14:58

Plaintiffs and Defense Designations = 00:03:05

Total Time = 00:42:49

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